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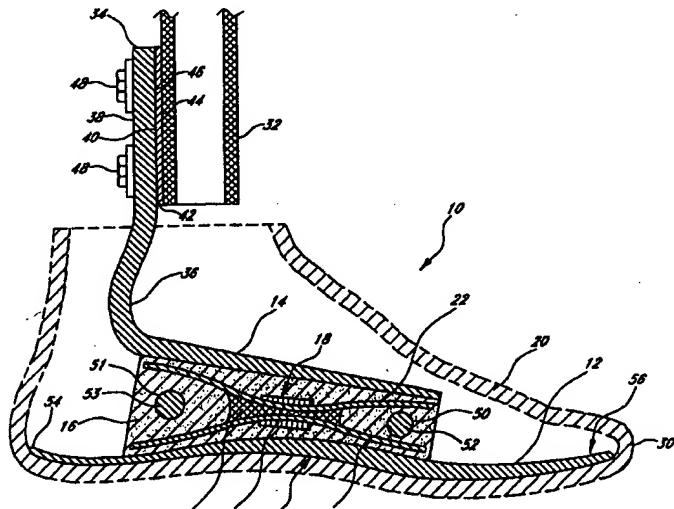
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/66	A1	(11) International Publication Number: WO 99/52476 (43) International Publication Date: 21 October 1999 (21.10.99)
(21) International Application Number: PCT/US99/07838		(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 9 April 1999 (09.04.99)		
(30) Priority Data: 60/081,472 10 April 1998 (10.04.98) US 09/138,357 21 August 1998 (21.08.98) US		
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(54) Title: FOOT PROSTHESIS HAVING CUSHIONED ANKLE



(57) Abstract

A simple, inexpensive prosthetic foot (10) is provided incorporating a cushioned ankle including an ankle block (16) formed of a resilient material or a bladder (19) having desired compliance and energy return characteristics. The ankle block (16) or bladder (19) is sandwiched between a foot plate element (12) and an ankle plate element (14). One or more optional spring elements (18) may be embedded inside the ankle block (16) or bladder (19) to increase the rigidity of the prosthetic foot (10) and to improve the degree of energy storage and return. The shape of the spring inserts (18) is preferably one that supports compression during relative angular rotation of the ankle plate element (14) and foot plate element (12), such as during toe and heel roll, and also vertical compression, such as in response to vertical shock loads.

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FOOT PROSTHESIS HAVING CUSHIONED ANKLE

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Background of the Invention**1. Field of the Invention**

The present invention relates to prosthetic feet and, more particularly, to a simply constructed, low-profile prosthetic foot having enhanced performance characteristics.

10 2. Description of the Related Art

In the prosthetics market, the conventional SACH (solid-ankle, cushion-heel) foot has been the most widely prescribed artificial foot over the past 35 years. The SACH foot generally includes a solid ankle and cushioned heel foot mounted to a limb along an approximate hinge axis taken through the ankle. The SACH foot has been popular precisely for its simplicity, and thus economy, but includes certain drawbacks in terms of dynamic response characteristics. Specifically, the low end SACH feet do not provide much energy storage and release, as do more sophisticated prosthetic feet.

20 Most modern foot prostheses incorporate some form of energy storage element for storing and releasing walking energy. Conventionally, this might consist of a spring-loaded ankle joint comprising metal coil springs or, more commonly, rubber compliance members. Inexpensive foot prostheses have also been devised having essentially a solid rubber or foam ankle block for storing and releasing walking energy. Such an ankle block has been disclosed in my issued patent titled PROSTHESIS WITH RESILIENT ANKLE BLOCK, U.S. Patent No. 5,800,569, the entirety of which is incorporated by reference. A solid, compressible ankle block may be secured between upper and lower support members to provide resilient compression and energy storage and release. The use of an ankle block member provides significant manufacturing and cost advantages. However, for certain applications it is difficult to attain a desired level of spring compliance and energy return characteristics using a solid ankle block due to the

inherent limitations of the materials involved in terms of elasticity, viscosity and maximum compression.

Therefore, it would be desirable to provide an ankle block having selectable compliance and energy return characteristics that may be varied over a wider range to accommodate the different weight, height and activity levels of amputees.

Summary of the Invention

In response to the problems with the prior art, the present invention provides a simple, inexpensive prosthetic foot incorporating an ankle block with spring inserts. The ankle block is formed of compressible material having desired compliance and energy return characteristics. The ankle block is sandwiched between a foot element and an ankle element. One or more spring inserts are embedded inside the ankle block to increase the rigidity of the prosthetic foot and to improve the degree of energy storage and return. The shape of the spring inserts is preferably one that supports compression during relative angular rotation of the ankle plate and foot plate elements, such as during toe and heel roll, and also vertical compression, such as in response to vertical shock loads.

In one aspect of the present invention, a basic prosthetic foot is provided having enhanced performance characteristics generally comprising a lower foot plate, an upper ankle plate, a foam ankle block joining the two plates, and a spring element embedded in the ankle block. Both the foot plate and the ankle plate are constructed of strong, flexible material, preferably a laminate of composite material. The foot plate is sized approximately equal to a human foot being replaced, while the ankle plate has a similar width, but has a shorter length than the foot plate. The ankle block has a length and width approximately equal to the ankle plate and is aligned therewith. The spring element comprises two relatively flat carbon fiber composite members secured at their middle and separated at their ends. This gives the spring element a preferable shape of a bowtie or double wishbone. Preferably, an attachment member couples the ankle plate to a stump or lower-limb pylon of the wearer. During walking, the combination of the resilient ankle block with embedded spring element and flexible plates provides a smooth rollover from a heel-strike to a toe-off position.

In another aspect, the ankle block of a prosthetic foot may be provided with cylindrical openings both in the fore and aft positions of the ankle block. These

openings enable the placement of additional inserts or stiffeners to give the block a desired rigidity. In a preferred embodiment, the foot element also has a tapered thickness. Further, the foot element comprises uplifted heel and toe ends and an arch region therebetween.

5 For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention have been described herein above. Of course, it is to be understood that not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will 10 recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

15 All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular preferred embodiment(s) disclosed.

Brief Description of the Drawings

20 FIGURE 1 is a perspective view of the prosthetic foot of the present invention.

FIGURE 2 is a cross-sectional view of the prosthetic foot of the present invention.

25 FIGURE 3 is a perspective view of the spring element embedded in the ankle block of the present invention.

FIGURE 4 is a side elevational view of the prosthetic foot more clearly showing a foot plate having a tapered thickness along its length.

FIGURE 5A is a sectional view of the prosthetic foot in a heel-strike position of a walking stride.

30 FIGURE 5B is a sectional view of the prosthetic foot in a flat position of a walking stride.

FIGURE 5C is a sectional view of the prosthetic foot in a heel-off position of a walking stride.

FIGURE 5D is a sectional view of the prosthetic foot in a toe-off position of a walking stride.

FIGURE 6 is a cross-sectional view of an alternative embodiment of a prosthetic foot of the present invention incorporating a modified spring element.

5 FIGURE 7 is a cross-sectional view of another alternative embodiment of a prosthetic foot of the present invention incorporating a modified ankle block.

FIGURE 8 is a cross-sectional view of another alternative embodiment of a prosthetic foot of the present invention incorporating a modified ankle block.

10 FIGURE 9 is a cross-sectional view of another alternative embodiment of a prosthetic foot of the present invention incorporating an inflatable bladder ankle block.

Detailed Description of the Preferred Embodiments

With reference to FIGURES 1 and 2, a first embodiment of a prosthetic foot 10 of the present invention is shown in a perspective view and a cross-sectional side view, respectively. The prosthetic foot 10 generally comprises a lower foot plate 12, an upper, smaller ankle plate 14, an ankle layer or block 16 made of resilient material, connecting the foot plate 12 to the ankle plate 14, and a spring element 18 embedded within the ankle block 16. The foot plate 12 has a length and width roughly equal to the approximate length and width of the particular wearer's amputated foot and sized to fit within an outer, flexible cosmesis 30, shown in phantom. The ankle plate 14 and the resilient ankle block 16 have approximately the same horizontal cross-sectional size. The ankle plate 14, ankle block 16, and spring element 18 are centered transversely with respect to and are generally positioned over the back half of the foot plate 12. The ankle block 16 is sandwiched between the foot plate 12 and the ankle plate 14 and is preferably glued or bonded to both plates using polyurethane adhesive or other known securement technologies.

The spring element 18 is a resilient support member inserted within the resilient ankle block 16. As shown in FIGURE 3, the spring element 18 is preferably comprised of upper and lower plate-like members 22 and 24, each of which is relatively flat and has a substantially rectangular vertical projection. These members are secured at their center by a fastener 26 and separated at ends 80 and 82. The upper member 22 preferably has a curvilinear concave upward

shape, while the lower member 24 preferably has a curvilinear concave downward shape. This gives the spring element 18 a substantially double wishbone or bowtie shape.

As shown in FIGURE 1, the spring element 18 is completely embedded within the ankle block 16 so as not to be visible from the outside. Referring to FIGURE 2, the spring element 18 extends substantially longitudinally across the length of the ankle block 16, and has a width substantially equal to the width of ankle block 16. The fastener 26 may comprise bolts, a weld, or any other fastening means as would be known to those skilled in the art. In the preferred embodiment, the fastener 26 is a strap which is laminated around the center portion of the two members 22, 24. A wedge member 28, preferably of a resilient elastomer, is placed between the two plate members 22, 24 to protect the inner surfaces of the members and to provide additional support to the spring element 18. The wedge 28 acts to provide leverage between the two plate members 22, 24, and enables adjustment of the flexing characteristics of the spring element 18, if desired. Alternatively, it may be bonded permanently in place or formed integrally with one or both of the plate members 22, 24, as desired. Although the spring element 18 has been described as having a double wishbone or bowtie configuration, other shapes and sizes may be appropriate for providing support to the ankle block 16. Furthermore, more than one spring element may be provided in the ankle block to provide support and energy return to the prosthetic foot 10.

As can be seen in FIGURES 1 and 2, the prosthetic foot 10 further comprises a pylon member 32 which can be secured to the stump of the amputee (not shown) and extends relatively downward therefrom in a generally vertical direction. The pylon member 32 in the preferred embodiment is of tubular construction having a substantially equal moment of inertia in all directions to restrict bending in all directions. The tubular member 32 is also preferably hollow so that it is relatively light in weight and utilizes less material which reduces the cost of production. The pylon member 32 is dimensioned so as to be interchangeable with a standard 30 mm pylon. Other configurations which impart rigidity, such as rectilinear cross sections having relatively larger moments of inertia about one or both transverse axes can also be utilized to obtain the benefits

discussed herein. A centerline 70 through pylon 32, shown in FIGURE 1, defines the downward direction of the application of force.

As shown in FIGURES 1 and 2, the ankle plate 14 is secured to the pylon member 32 through a vertically oriented upper attachment member 34. The upper attachment member 34 is attached to a curvilinear ankle section 36, which is connected to the ankle plate 14. Preferably, these three pieces are monolithically formed with one another for optimum strength and durability. The attachment member 34 has a rearward surface 38, as shown in FIGURE 2, and a forward surface 40 substantially parallel thereto. The attachment member 34 is substantially rigid and capable of sustaining torsional, impact and other loads impressed thereupon by the prosthesis. In addition, the inherent rigidity of attachment member 34 prevents it from being distorted in any substantial way and causes the effective transmission of the aforesaid loads imposed thereupon to a suitable ancillary prosthetic pylon 32.

With reference to FIGURE 2, the attachment member 34 is in the preferred embodiment vertically oriented so that it may be secured to the pylon member 32. A coupling device 42 is positioned at the lower end of the pylon member 32 which provides a flat surface upon which the vertical attachment member 34 can be secured. The coupling device 42 has one attachment surface 44 which mates with the cylindrical outer surface of the pylon member 32 and a second substantially flat attachment surface 46 which mates with the attachment member 34. In the preferred embodiment, attachment surface 44 is curved to mate with the outer surface of the tubular pylon member 32, and attachment surface 46 is flat to accommodate the forward surface 40 of the attachment member 34.

Desirably, the coupling device 42 is welded or bonded to the pylon member 32 and has two holes (not shown) into which two bolts 48 can be inserted and secured. The attachment member 34 also has two holes (not shown) which align with the holes on the coupling device to place and secure the two bolts 48 through the attachment member 34 and the coupling device 42. Other methods of securing the pylon member to the foot portion are contemplated, such as those disclosed in my prior issued U.S. Patent No. 5,514,186, the entirety of which is incorporated by reference, as well as those utilizing integrally formed constructions.

As stated, the attachment member 34 monolithically formed with the ankle plate 14 is vertically aligned so that it extends relatively downward from the coupling device 42 on the pylon member 32. As shown in FIGURE 2, the thickness of the attachment member 34 along this vertical section is relatively greater than the thickness of the ankle plate 14 substantially horizontally aligned along the foot portion. The attachment member 34 is also made relatively thicker to support the vertical load imposed on the prosthetic device as well as to restrict undue bending at this juncture. The entire upper vertically-aligned section of attachment member 34 is preferably of substantially uniform thickness and width.

The tubular pylon member 32 is preferably removable from the prosthetic device such that the pylon member can be replaced without replacing the remainder of the prosthetic device. This permits Applicant's invention to be utilized in a broader range of applications. For instance, the tubular member of Applicant's invention can be cut and adapted for use by amputees having different stump lengths including growing amputees. The prosthetist merely needs to cut a standard tubular pylon to the appropriate length. Moreover, this eliminates the need to manufacture as a part of the prosthesis a long rigid leg section. Thus, fewer materials are needed to manufacture the prosthesis of Applicant's invention resulting in reduced manufacturing costs.

The preferred embodiment further comprises cylindrical slots or openings 50, 51 in the fore and aft portions of the ankle block 16, respectively, as shown in FIGURE 2, to accommodate insertion of stiffeners 52, 53. The cylindrical openings 50, 51 are disposed horizontally in a direction generally transverse to a forward walking motion, and between upper and lower plate members 22 and 24. Stiffeners 52, 53 can be removably placed in these openings to provide additional support and rigidity to the prosthetic foot 10, and also to modify the spring characteristics of the prosthetic foot. For instance, additional energy storage and return can be provided for a more active amputee by inserting stiffeners 52, 53 into ankle block 16 having a higher spring constant. On the other hand, when more control is desired, stiffeners with a lower spring constant may be inserted to produce an ankle block 16 with greater dampening characteristics. Alternatively, the cylindrical openings 50, 51 may remain empty, thereby making the compliance characteristics dependent solely on the ankle block 16 and the spring element 18.

Preferred Materials and Fabrication

Both the foot plate 12 and the ankle plate 14 are preferably formed of a flexible material so that flexing of the plates tends to relieve extreme shear stresses applied to the interfaces between the ankle block 16 and the plates 12, 14. Both 5 the foot plate 12 and the ankle plate 14 are preferably constructed of fiberglass which provides strength and flexibility. The preferred material for the ankle plate 14 and the foot plate 12 is a vinyl ester based sheet molding compound, such as Quantum #QC-8800, available from Quantum Composites of Midland, Michigan. Alternatively, the plates may be formed by a plurality of lamina embedded in an 10 hardened flexible polymer. In other arrangements, the plates may be formed of other materials such as carbon fiber composites as may be apparent to one skilled in the art. The desirable properties of the plates are that they are relatively resilient so as to withstand cracking upon application of repeated bending stresses yet have sufficient flexibility to enhance the performance characteristics felt by the 15 wearer in conjunction with the properties of the resilient ankle block. The pylon member 32 is preferably made of a stiff material such as a laminate of fiber reinforced composite. Stiffness in the pylon member 32 can also be provided by a stiffer and more dense material.

The ankle block 16 is sandwiched between the foot plate 12 and the ankle 20 plate 14 as shown in FIGURES 1 and 2 and is preferably bonded to both plates. The ankle block is preferably formed of urethane, rubber or other suitable material having desired compliance and energy return characteristics. A preferred material for the ankle block is expanded polyurethane foam such as cellular Vulkolka® Pur-Cell No. 15-50, with a density of approximately 500 kg/m³ as available from 25 Pleiger Plastics Company of Washington, Pennsylvania. Alternatively, the ankle block 16 may be molded or fabricated from a wide variety of other resilient materials as desired, such as natural or synthetic rubber, plastics, honeycomb structures or other materials. Cellular foam, however, provides a high level of compressibility with desirable visco-elastic springiness for a more natural feeling 30 stride without the stiffness drawbacks and limited compression associated with solid elastomeric materials. Furthermore, the cellular nature of a foam block makes it lighter than solid elastomers. Foam densities between about 150 and 1500 kg/m³ may be used to obtain the benefits of the invention taught herein.

The spring element 18 is preferably made from a highly resilient material that is capable of supporting compression during relative angular rotation of the upper and lower members 12 and 14, such as during toe and heel roll, and also vertical compression such as in response to vertical shock loads. One preferred material is carbon fiber composites such as woven fiber mats and chopped fiber in an epoxy matrix. However, other materials with similar strength and weight characteristics will be known to those skilled in the art and may be used with efficacy. For instance, other filament types may be used, such as glass, Kevlar and nylon by way of example, to ensure lightweight and structural and dynamic characteristics consistent with the needs of a particular amputee. The wedge 28 may be fabricated from a wide variety of resilient materials, including natural and synthetic rubber, elastomeric polyurethane, or the like.

The ankle block 16 containing spring element 18 may be fabricated by injecting a polyurethane elastomer into a mold allowing it to cure. The spring element 18 may be inserted into the mold prior to injection of the polyurethane so that during curing, the polyurethane bonds to the spring member. Cylindrical slots or openings 50, 51 for insertion of stiffeners 52, 53 may be provided in ankle block 16 by inserting cylindrical plugs into the block prior to injection of polyurethane. Alternatively, openings may be provided in the block after curing simply by cutting or drilling away portions of the ankle block.

The stiffeners provided in the openings are preferably tubes of foam material having a density chosen according to desired compliance characteristics. A preferable material is expanded polyurethane having a foam density between about 150 and 1500 kg/m³. More preferably, a density of about 250 to 750 kg/m³ is preferred to provide adequate adjustment of the energy storage and return characteristics of the foot.

Preferred Dimensions

As illustrated in FIGURE 4, the foot plate 12 is preferably of curvilinear shape. The thickness t of foot plate 12 is preferably tapered along its length, and the tapered profile corresponds approximately to the weight of the amputee. That is, for a heavier amputee, the thicknesses along the length would be greater than for a lighter weight amputee. Generally, the weight groups may be classified as light, medium, or heavy.

Table I below presents preferred groupings, as module sizes C/D/E, of cosmesis sizes corresponding to a male "A" width shoe last. The sizes are presented by length L, width B at the forefoot and width H at the heel of the cosmesis.

5

Table I. Cosmesis Sizes for Male "A" Width Shoe Last

MODULE	LENGTH L (cm)	WIDTH B (cm)	WIDTH H (cm)
C	22	2.88	2.19
	23	3.00	2.25
	24	3.12	2.31
D	25	3.25	2.44
	26	3.38	2.50
	27	3.50	2.56
E	28	3.62	2.69
	29	3.75	2.75
	30	3.88	2.81

Table II below presents preferred module sizes for various weight groups of amputees.

Table II. Modules vs. Weight Groups

MODULE	WEIGHT GROUP		
	LIGHT	MEDIUM	HEAVY
C	CL	CM	-
D	DL	DM	DH
E	-	EM	EH

25

Table III below presents preferred taper thicknesses (t) for an average or "DM" size foot plate 12, taken at positions spaced by distance x = 1 inch (2.54 cm).

30

Table III. Taper Thickness t for DM Foot Plate

POSITION (x = 2.54 cm)	THICKNESS t (cm)
a	0.16
b	0.16
c	0.32
d	0.52
e	0.69
f	0.78
g	0.71
h	0.60
i	0.48
j	0.28

The foot plate 12 has a heel end 54, toward the left in FIGURE 4, which
 15 is concave-upward or slightly uplifted from a horizontal plane P_1 tangential to the
 heel end 54 of the foot plate 12. Similarly, a toe end 56, to the right of FIGURE
 20 4, is concave upward or somewhat uplifted from a horizontal plane P_2 tangential
 to the front portion of the foot plate 12. An arch section 58 is formed between the
 heel and toe ends and is preferably concave-downward, as shown.

It is understood that within the cosmesis 30 (not shown), the tangent plane
 25 P_1 of the heel end 54 is slightly raised a distance y relative to the tangent plane P_2
 of the toe end 56, as shown. The DM-sized foot plate of Table III, for example,
 has $y = 0.5$ inches (1.27 cm). The foot plate 12 is preferably 0.25 inches (0.63
 30 cm) from the bottom or sole of the cosmesis 30. The cosmesis 30 may be insert
 molded using an anatomically sculpted foot shape, with details and sizing based
 on a master pattern and/or digitized data representing typical foot sizes.

An intermediate region 58 comprising the arch portion of the foot plate 12
 has the greatest thickness of the foot plate 12. The curvature of the arch region
 30 58 is defined by the cosmesis or shoe sole profile, and generally corresponds to
 selected ranges of human foot lengths.

The foot plate 12 of prosthesis 10 preferably has a length between about 5
 and 15 inches (about 13 and 38 cm), more preferably between about 8 and 12
 inches (about 20 and 30 cm) for the foot sizes given in Table I. The width of foot

plate 12 is preferably about 1 to 4 inches (about 2.5 to 8 cm). For the example given in Table III for a DM-sized foot plate 12, the length of the plate 12 is approximately 9 inches (about 23 cm) and its width is about 2 inches (about 5 cm). The foot plate 12 has a thickness between about 0.05 and 0.4 inches (about 0.1 and 1 cm), which more preferably may be tapered as indicated in Table III.

The ankle plate 14 of prosthesis 10 is substantially planar, and is preferably shorter in length than the foot plate 12 and has a thickness also defined by the weight group of the wearer. The thickness of the ankle plate is preferably about 0.05 to 0.4 inches (0.1 to 1 cm). More preferably, the corresponding ankle plate 14 in the present example is about 0.2 inches (about 0.5 cm) thick at rear portion 62, tapering to a thickness of about 0.1 inches (about 0.25 cm) at front portion 60. The ankle plate 14 preferably has a length of about 3 to 7 inches (about 8 to 18 cm) and a width of about 1 to 3 inches (about 2.5 to 8 cm), more preferably having length-width dimension of approximately 5 x 2 inches (about 13 x 5 cm).
10
15 The ankle plate 14 is positioned at an angle such that its front tip 60 is located closer to the foot plate 12 than its rear tip 68. Relative to plane P₃ shown in FIGURE 4, the rear tip is preferably raised an angle γ of about 5 to 30 degrees, and more preferably, about 10 degrees.

The ankle block 16 is generally sized such that its upper surface is planar and corresponds to the length and width of the ankle plate 14. The lower surface of the ankle block 16 is substantially curvilinear to mate with the curvilinear surface of foot plate 12. In the present example, the block 16 has a preferred thickness, at its front 66, of about 1 to 3 inches (about 2.5 to 8 cm), more preferably about 1.3 inches (about 3.4 cm). Its thickness tapers to a minimum of about 0.5 to 1 inch (about 1 to 2.54 cm), more preferably about 0.8 inches (about 2 cm) adjacent arch portion 58. The rear 64 of the block 16 is preferably about 1 to 4 inches (about 2.5 to 10 cm) thick, more preferably about 2.6 inches (about 6.6 cm) thick, which is about twice the thickness of the front portion 66 of the block 16. This gives the ankle block a substantially wedge shape. The greater thickness at the rear of block 16 is provided to impart additional support in the rear portion 64 of the ankle block due to greater compressive forces on the rear of the foot prosthesis caused by off-axis application of force relative to axis 70 during heel strike (see FIGURE 5A).

The ankle block 16 may be provided in varying heights or thicknesses, as desired, but is most effective with a thickness of between about 1 and 4 inches (about 2.54 and 10 cm). The front portion and rear surfaces of ankle block 16 are preferably angled according to the angle γ defined by the plane P_3 and the ankle plate 14. In other words, the ankle block has front and rear surfaces which are preferably sloped forward at an angle γ from vertical. The ankle block thus provides a relatively stiff, yet flexible ankle region which can be customized for various wearers. Heavier wearers may require a denser resilient material for the ankle block, while lighter wearers may require a less dense material or less thickness.

As shown in FIGURES 2 and 3, the spring element 18 is positioned in the ankle block such that the center of the spring element 18, at the position of fastener 26, is located approximately above the arch portion 58 of foot plate 12. The two members 22, 24 of the spring element 18 preferably have a constant thickness of about 0.05 to 0.2 inches (about 0.1 to 0.5 cm). The distance between the two members at front end 82, when no load is impressed onto the foot 10, is preferably about 0.5 and 2 inches (about 1 to 5 cm), more preferably about 0.7 inches (about 1.8 cm). At rear end 80, when no load is impressed on the foot 10, the distance between members 22 and 24 is about 1 to 3 inches (about 2.5 to 7.5 cm), more preferably about 1.4 inches (about 3.5 cm). As described in further detail below, when the foot is in a heel-strike position, the rear end 80 of the spring element is compressed. When the foot is in a toe-off position, the forward end 82 of the spring element is compressed.

The lengths, widths and thicknesses of the foot plate 12, ankle plate 14, ankle block 16 and spring element 18 may be customized for the wearer according to his/her foot size as well as the approximate weight group of the wearer. Likewise, the material choice and size for these elements may be varied according to the wearer's foot size and weight.

The cylindrical openings 50, 51 provided in the fore and aft portions of ankle block 16 preferably have a diameter of about 0.1 to 0.4 inches (about 0.25 to 1 cm), and more preferably, about 0.2 inches (about 0.5 cm). While the openings 50 and 51 shown in FIGURE 2 have the same diameter, the diameters of the openings may be different to accommodate different sized stiffeners. For

instance, the diameter of opening 51 may be made larger than the diameter of opening 50 to correspond with the greater volume of ankle block 16 in rear portion 64.

Performance Characteristics

- 5 To more fully explain the improved performance characteristics of the present prosthetic foot 10, FIGURES 5A-5D show "snapshots" of a prosthetic foot in several positions of a walking stride. More particularly, FIGURE 5A shows a heel-strike position, FIGURE 5B shows a generally flat or mid-stance position, FIGURE 5C shows a heel-off position, and FIGURE 5D shows a toe-off position.
- 10 Throughout the various positions shown for a walking stride, the present prosthetic foot 10 provides a smooth and generally life-like response to the wearer. During a walking stride, the ankle block 16 transmits the forces imparted thereon by the foot plate 12 and ankle plate 14, and experiences a gradual rollover, or migration of the compressed region, from rear to front.
- 15 With specific reference to FIGURE 5A, a first position of a walking stride generally entails a heel strike, wherein the wearer transfers all of his or her weight to the heel of the leading foot. In this case, a rear portion 54 of the foot plate 12 comes in contact with a ground surface 68, albeit through the cosmesis 30. The flexible nature of the foot plate 12 allows it to bend slightly in the rear portion 54,
- 20 but most of the compressive stresses from the weight of the wearer through the prosthetic foot 10 to the foot plate 12 are absorbed by a rear region 64 of the ankle block 16 with spring element 18. The spring element 18 in the rear portion contracts, such that the distance between members 22 and 24 at rear end 80 decreases. In a front region 66 of the ankle block 16, the spring element 18 may expand slightly such that the distance between members 22 and 24 at front end 82 increases. Front portion 66 of the ankle block 16 experiences a stretching, or tension, due to the attachment along the entire lower edge of the ankle block with the foot plate 12, while rear portion 64 experiences compression. The contraction of the spring element 18 at end 80 and ankle block 16 at end 64 allows the prosthesis 10 to absorb and store energy from the compressive stresses during heel strike. Further, a slight amount of bending may occur in a rear region 68 of the ankle plate 14. The rear stiffener 53 between members 22 and 24 is compressed so as to provide necessary support to the foot prosthesis and to prevent separation
- 25
- 30

of the members 22, 24 from the wedge 28. Front stiffener 52 is slightly stretched substantially vertically due to the tension forces at front portion 66 of ankle block 16.

Next, in FIGURE 5B, the wearer reaches a generally flat-footed or midstance position, whereby the foot plate 12 contacts the ground 68 along substantially its entire length, again through the cosmesis 30. In this position the weight of the wearer is directed substantially downwardly, so that the compression along the length of the ankle block 16 is only slightly greater in the rear portion 64 than in front portion 66, due to the off-center application of force. In both the fore and rear ends of spring element 18, the members 22 and 24 are compressed towards each other, with the rear end 80 being slightly more compressed from its original position than the forward end 82. Likewise, stiffeners 52 and 53 are compressed due to the downward application of force. Although this view freezes the compressive stress distribution as such, in reality the weight of the wearer is continually shifting from behind the centerline 70 of the attachment member 34 to forward thereof. Thus, as the wearer continues through the stride, the compression of the ankle block 16 and the elements embedded within travels from the rear portion 64 toward the front portion 66. This migration of the compressed region can be termed "rollover."

In a next snapshot of the walking stride, FIGURE 5C shows the prosthetic foot 10 in a "heel-off" position. This is the instant when the wearer is pushing off using ball 72 and toe 74 regions of the foot. Thus, a large compressive force is generated in the front region 66 of the ankle block 16, causing the rear region 64 to experience a large amount of separation or tension. Similarly, the spring element 18 at the rear end 80 expands between the two members 22, 24, while it compresses in the front end 82. The front tip 56 of the foot plate 12 may bend substantially to absorb some of the compressive stresses. Likewise, the front tip 60 of the ankle plate 14 may bend somewhat at this point. It is important to note that although the ankle block 16 absorbs a majority of the compression generated by the wearer, the foot plate 12 and ankle plate 14 are designed to work in conjunction with the resilient ankle block and spring element and provide enhanced dynamic performance. Further, the flexing of the foot plate 12 and ankle plate 14 relieves some of the extreme shear stresses applied to the interfaces between the

5 ankle block 16 and plates, thus increasing the life of the bonds formed therebetween. The stiffener 52 located in the front 66 of the ankle block 16 compresses so as to limit compression of front end 82, giving the wearer balance and to prevent separation of the members 22, 24 from the wedge 28. Stiffener 53 extends due to the separation of ankle block 16 in rear portion 64.

10 In FIGURE 5D, a final position of the walking stride is shown, wherein the prosthetic foot 10 remains in contact with the ground 68, but some of the weight of the wearer is being transferred to the opposite foot, which has now moved forward. In this "toe-off" position, there is less bending of the front tip 56 of the foot plate 12 and less compression of the front portion 66 of the ankle block 16 and front end 82 of spring element 18. Likewise, the front tip 60 of the ankle plate 14 may flex a slight amount, depending on the material and thickness utilized. The region of highest compression of the ankle block 16 remains at the farthest forward region 66, but it is reduced from the compression level of the heel-off position of FIGURE 5C. Thus, the rear portion 64 of the ankle block 16 experiences a small amount of tension or spreading.

15

20 It can now be appreciated that the "feel" of the present prosthetic foot is greatly enhanced by the cooperation between the foot plate, ankle plate, ankle block and spring inserts. As the wearer continues through the walking stride the dynamic response from the prosthetic foot is smooth as the ankle block with spring inserts compresses in different regions. Further, the flexing of the ankle and foot plates assist in smoothly transmitting the various bumps and jars found in uneven walking surfaces.

25 Alternative Embodiments
It will be appreciated that many alternative embodiments of a prosthetic foot having features and advantages in accordance with the present invention may also be constructed and used with efficacy. One such alternative embodiment is shown in FIGURE 6. Reference numerals for FIGURE 6 generally correspond to the reference numerals used in FIGURES 1-5D for like elements. Thus, the prosthetic foot 10 shown in FIGURE 6 generally comprises a lower foot plate 12, an upper, smaller ankle plate 14, an ankle layer or block 16 made of resilient material, connecting the foot plate 12 to the ankle plate 14, and a spring element 18 embedded within the ankle block. The foot plate 12 has a length and width

30

roughly equal to the approximate length and width of the particular wearer's amputated foot and sized to fit within an outer, flexible cosmesis 30, shown in phantom. As shown in FIGURE 6, the ankle plate 14 has a substantially arcuate curvature extending from the integrally formed attachment member 34 to the front of the ankle plate 14.

More particularly, the spring element 18 as illustrated in FIGURE 6 is a resilient support member inserted within the resilient ankle block 16. The spring element 18 shown in FIGURE 6 is preferably a plate-like member with a curvilinear concave downward shape and a substantially rectangular vertical projection. The spring element 18 is preferably made from a carbon fiber composite material such as described hereinbefore, although other similar materials may be used as well.

FIGURE 7 illustrates another alternative embodiment of the invention. Again, like reference numerals are generally used to indicate like elements. Thus, the prosthetic foot 10 shown in FIGURE 7 generally comprises a lower foot plate 12, an upper, smaller ankle plate 14, and an ankle layer or block 16 made of resilient material, such as solid or foam rubber or polyurethane, and connecting the foot plate 12 to the ankle plate 14. The foot plate 12 has a length and width roughly equal to the approximate length and width of the particular wearer's amputated foot and sized to fit within an outer, flexible cosmesis 30, shown in phantom. As shown in FIGURE 7, the ankle plate 14 transitions into a substantially arcuate or curved ankle section 36 which is preferably integrally formed between the attachment member 34 and the ankle plate 14.

FIGURE 8 illustrates yet another alternative embodiment of the invention. Again, like reference numerals are generally used to indicate like elements. Thus, the prosthetic foot 10 shown in FIGURE 8 generally comprises a lower foot plate 12, an upper, smaller ankle plate 14, and one or more ankle blocks 16a, 16b made of resilient material, such as solid or foam rubber or polyurethane, and connecting the foot plate 12 to the ankle plate 14. If desired, the posterior ankle block 16a may have a density or compliance characteristic which is different than that of the anterior ankle block 16b, so as to render it more soft and more compliant, for example, than the anterior ankle block 16b. For instance, this configuration could provide a more compliant heel response during heel strike.

Ankle blocks 16a, 16b may be formed integrally or separately, as desired or as expedient. Preferably, they are positioned closely adjacent to one another so as to occupy substantially the entire space between the foot plate 12 and the ankle plate 14. The foot plate 12 preferably has a length and width roughly equal to the approximate length and width of the particular wearer's amputated foot and sized to fit within an outer, flexible cosmesis 30, shown in phantom. As shown in FIGURE 8, the ankle plate 14 transitions into a substantially arcuate or curved ankle section 36 which is preferably integrally formed between the attachment member 34 and the ankle plate 14.

FIGURES 9 and 10 illustrate two other possible alternative embodiments of the invention. Again, like reference numerals are generally used to indicate like elements. Thus, the prosthetic foot 10 shown in FIGURE 9 generally comprises a lower foot plate 12, an upper, smaller ankle plate 14, and, in this case, an inflatable bladder 19 disposed between the foot plate 12 and the ankle plate 14. The bladder 19 has the further advantage in that it enables the patient or prosthetist to vary the performance characteristics of the prosthesis by adjusting the pressure in the bladder 19. This may be accomplished, for example, through the provision of a valve means 21, which is provided in communication with the bladder 19. In a preferred embodiment, the valve 50 is adapted to receive a needle from an air pump (not shown) or from a CO₂ cartridge (not shown), and may be suitably disposed on bracket 27, as illustrated in FIGURES 9 and 10. The valve 21 may be operatively connected to bladder via tubing or other suitable communication passage.

The bladder 19 may be secured via adhesive or other suitable affixing means to the upper ankle plate 14 and the lower foot plate 12 so as to provide substantially the sole means of connection and support therebetween. Optionally, one or more retaining straps 23 may be used to provide primary or secondary connection support, as needed or desired. Strap 23 may be fabricated from any number of suitably tough, flexible materials such as epoxy-impregnated canvas or the like. For example, straps 23 may be operatively attached to the forefoot portion of the prosthetic foot 10 as illustrated in FIGURE 9 via adhesive, or nuts and bolts, or may be releasably attached around the structural member 12, 14 through the provision of Velcro®-type fasteners or similar expedient.

The straps 23 provide a number of benefits. For example, if juxtaposed to a bladder member 19, the strap may be appropriately tightened to 'flatten' the bladder, thus increasing the contact area between the structural members 12, 14 and the bladder. Moreover, restraining means such as the straps 23 may be incorporated to restrict the distance that the associated structural members 12, 14 may move from one another. The straps 23 may also be utilized to prevent undesirable excessive loading and stressing of the structural members 12, 14 and/or the bladder 19.

The bladder 19 is preferably fabricated from a suitably strong, flexible, leak-proof, lightweight material such as urethane or the like. By way of example, the bladder may be formed by heat sealing appropriately sized and shaped pieces of urethane sheet to each other. Suitable thicknesses of urethane sheet material have been found to be 0.01 to 0.02 inches (0.25 - 0.50 mm), but a wide range of suitable thicknesses and materials may also be utilized with efficacy. Bladder pressures of up to 80 psi (5.5 bar) have been utilized with efficacy.

The bladder 19 is preferably enwrapped in a covering material of Kevlar or similarly strong material to prevent the bladder 19 from exploding under high pressures and to help define the final inflated shape of the bladder. In preferred embodiments, a covering may include top and bottom sections which are stitched together at the perimeter 25 of the bladder 19. Those skilled in the art will understand that a variety of covering materials and methods of fabrication and assembly thereof may be also utilized with efficacy, without departing from the teachings of the invention.

Bladder 19 may enclose air, CO₂, or a similar gas-like substance, or may alternatively enclose liquids or gels such as water, silicone, or the like. Any such assembly is preferably selected and adjusted to provide the desired deformability and consequent 'cushioning' effect or energy-storing, absorption and release.

The bladder 19 may comprise a single chamber bladder, as illustrated in FIGURE 9, or, optionally, it may comprise a multiple chamber bladders with or without venting provided between adjacent chambers. For example, the bladder could be bifurcated into anterior and posterior chambers or portions 19a, 19b such that the posterior portion 19a can be adjusted to have a compliance characteristic which is different than that of the anterior portion 19b, so as to render it more soft

and more compliant, for example, than the anterior portion. This may be desirable, for instance, to provide a more compliant heel response during heel strike. If desired or expedient, the bladder 19 may be tapered in shape so as to permit operative and proper alignment of the bladder between the ankle plate 14 and the
5 foot plate 12.

Optionally, a spring element identical or similar to that illustrated and described above in connection with FIGURES 2-5, may be provided substantially completely within the bladder 19 (FIGURE 9) so as to provide primary or supplemental support between the foot and ankle plates, as desired. For, example,
10 the spring element may comprise two relatively flat carbon fiber composite members secured at their middle and separated at their ends. This gives the spring element a preferable shape of a bowtie or double wishbone. During walking, the combination of the resilient spring element and inflatable bladder provides a smooth and adjustable rollover characteristic from a heel-strike to a toe-off, as
15 desired.

The foot plate 12 preferably has a length and width roughly equal to the approximate length and width of the particular wearer's amputated foot and sized to fit within an outer, flexible cosmesis 30, shown in phantom. As shown in FIGURES 9 and 10, the ankle plate 14 transitions into a substantially arcuate or
20 curved ankle section 36 which is preferably integrally formed between the attachment member 34 and the ankle plate 14.

Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.
25

WHAT IS CLAIMED IS:

1. A prosthetic foot comprising:

5 a foot plate element having a length approximately equal to the length of a human foot, the foot plate element comprising a resilient material capable of flexing along its length;

an ankle plate element having a length substantially shorter than the foot plate element and being disposed above and generally over said foot plate and spaced therefrom;

10 a cushioned ankle member comprising a bladder or an ankle block formed of relatively soft, compressible material sandwiched between the ankle plate element and the foot plate element, and including at least one spring element embedded substantially completely within the bladder or the ankle block, the cushioned ankle member providing substantially the sole means of support and connection between the foot plate element and the 15 ankle plate element;

whereby the foot plate element and the ankle block flex in a cooperative manner to provide substantially smooth and continuous rollover transition from heel-strike to toe-off.

20 2. The prosthetic foot of Claim 1, wherein the foot plate element has a tapered thickness along its length, such that the thickness increases from a heel section to an arch section and decreases from the arch section to a toe section.

3. The prosthetic foot of Claim 1, wherein the cushioned ankle member comprises a single monolithic block of relatively soft, compressible material.

25 4. The prosthetic foot of Claim 1, wherein the cushioned ankle member comprises at least two portions of relatively soft, compressible material disposed closely adjacent one another and sandwiched between the ankle plate element and the foot plate element, the ankle block providing substantially the sole means of support and connection between the foot plate element and the ankle plate element and wherein at least one portion of the ankle block is formed of a material having 30 a compliance characteristic which is different from that of at least one other portion of the ankle block.

5. The prosthetic foot of Claim 4, wherein at least one portion of the ankle block is made of a foam material having a density between about 150 and 1500 kg/m³.

5 6. The prosthetic foot of Claim 1, wherein the cushioned ankle member comprises a compressible bladder disposed between the upper ankle plate and the lower foot plate and separating the upper plate from the lower plate, the bladder providing substantially the sole means of support between the foot plate and the ankle plate.

10 7. The prosthetic foot of Claim 6, wherein the bladder comprises two or more chambers and wherein at least one of the chambers may be adjusted to have a compliance that is different than the compliance of at least one other chamber.

15 8. The prosthetic foot of Claim 1, wherein the spring element comprises upper and lower spring members secured at their center by a fastener and separated at their ends.

9. The prosthetic foot of Claim 8, wherein the upper spring member is substantially curvilinear concave upward and the lower spring member is substantially curvilinear concave downward.

20 10. The prosthetic foot of Claim 1, wherein the ankle plate transitions into a substantially arcuate or curved ankle section and a substantially vertical attachment section each of which are integrally formed with the ankle plate.

11. The prosthetic foot of Claim 10, wherein the ankle section curves initially rearward and upward and then forward and upward terminating in an upwardly vertical attachment section.

25 12. The prosthetic foot of Claim 11 attached to the distal end of a substantially cylindrical vertical pylon.

30 13. The prosthetic foot and pylon of Claim 12 further comprising a coupling member disposed between the attachment section and the cylindrical pylon and having at least one substantially flat mating surface and an oppositely disposed cylindrical mating surface for providing secure connection between said prosthetic foot and said pylon.

14. The prosthetic foot of Claim 1 in combination with a cosmesis cover.

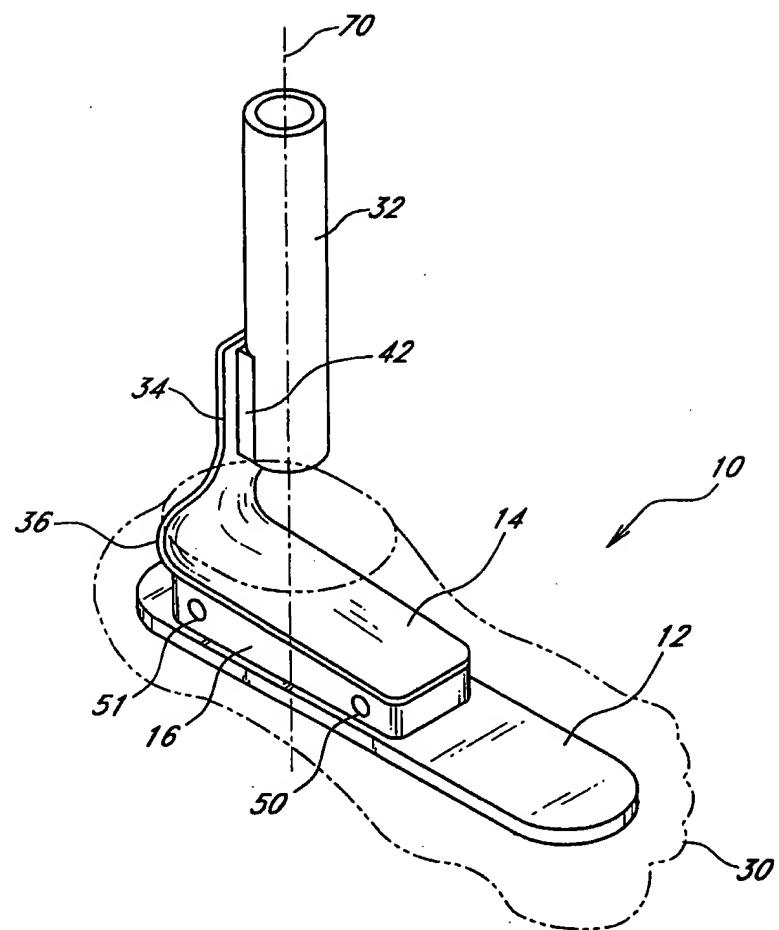
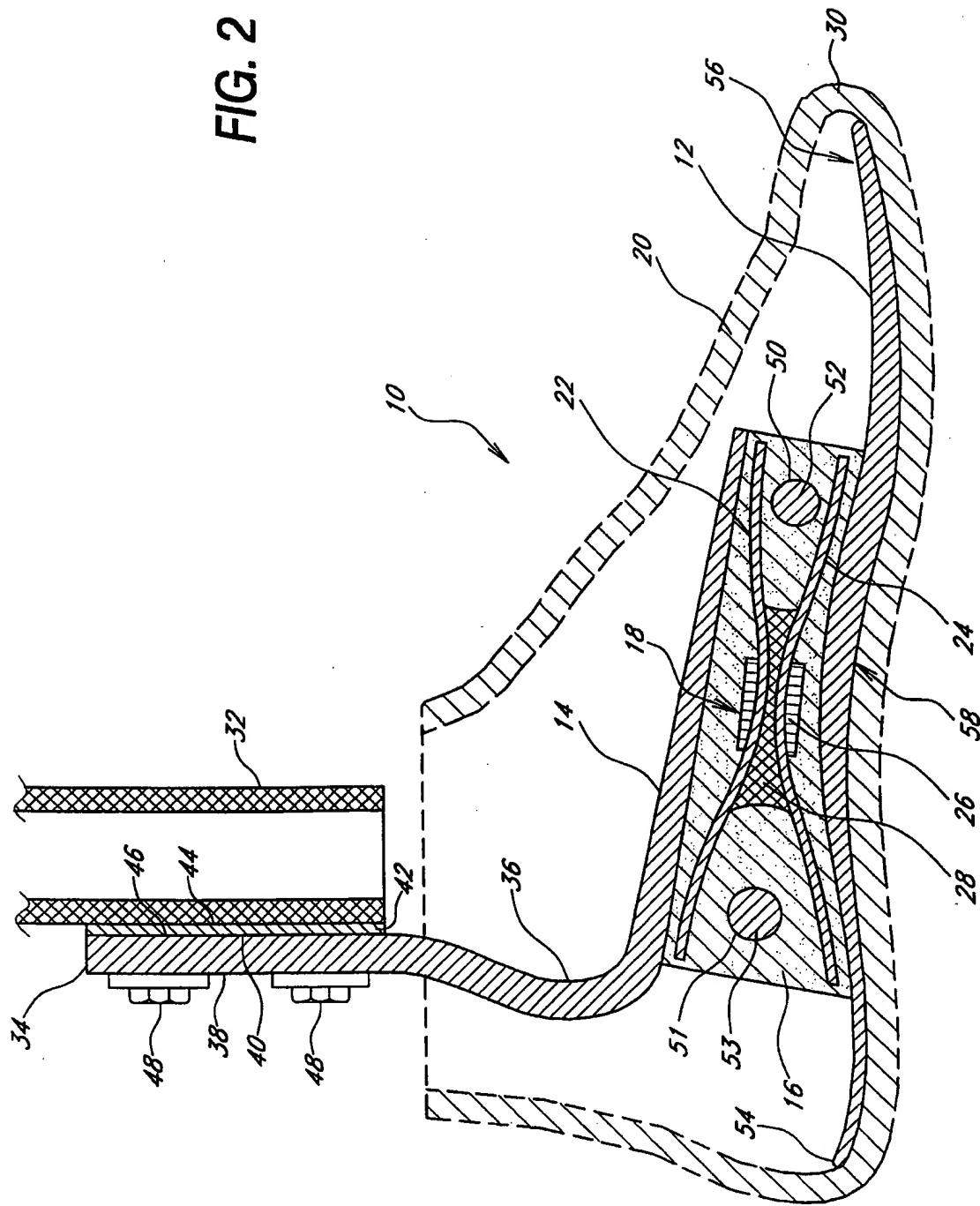


FIG. 1

FIG. 2



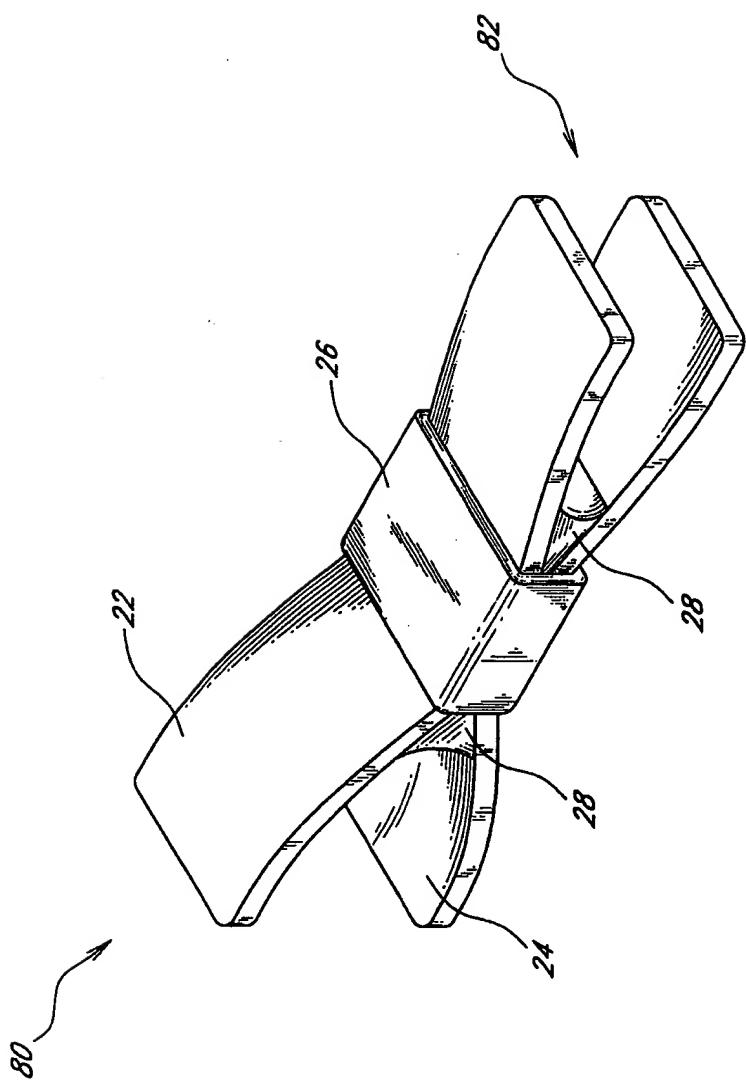


FIG. 3

FIG. 4

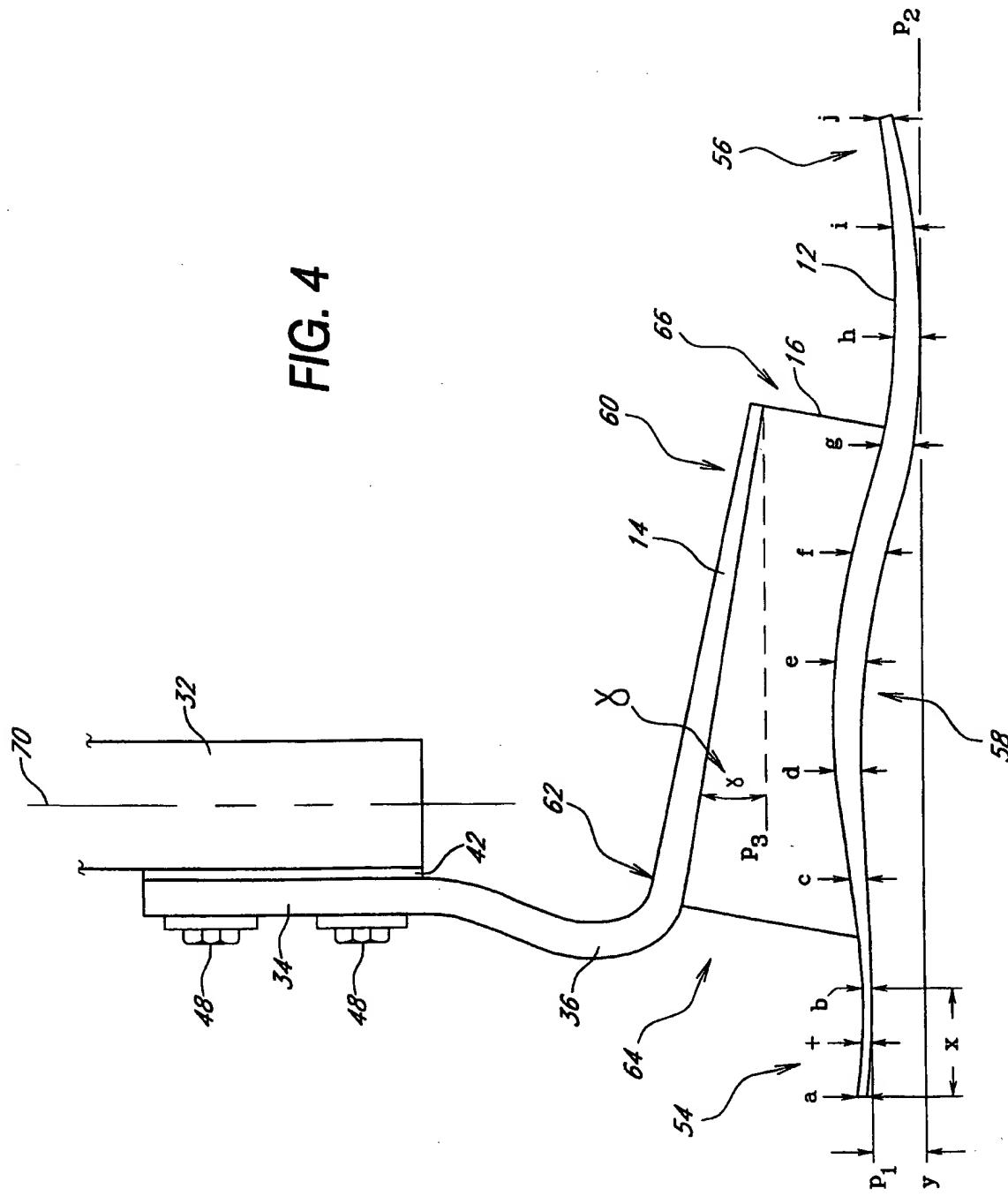
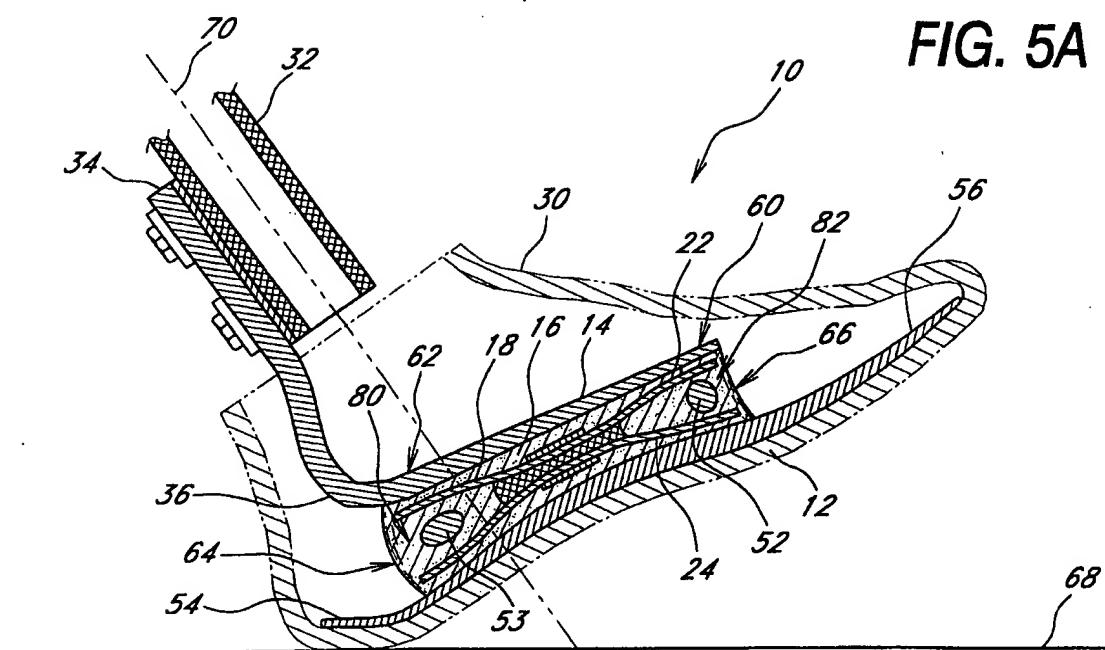
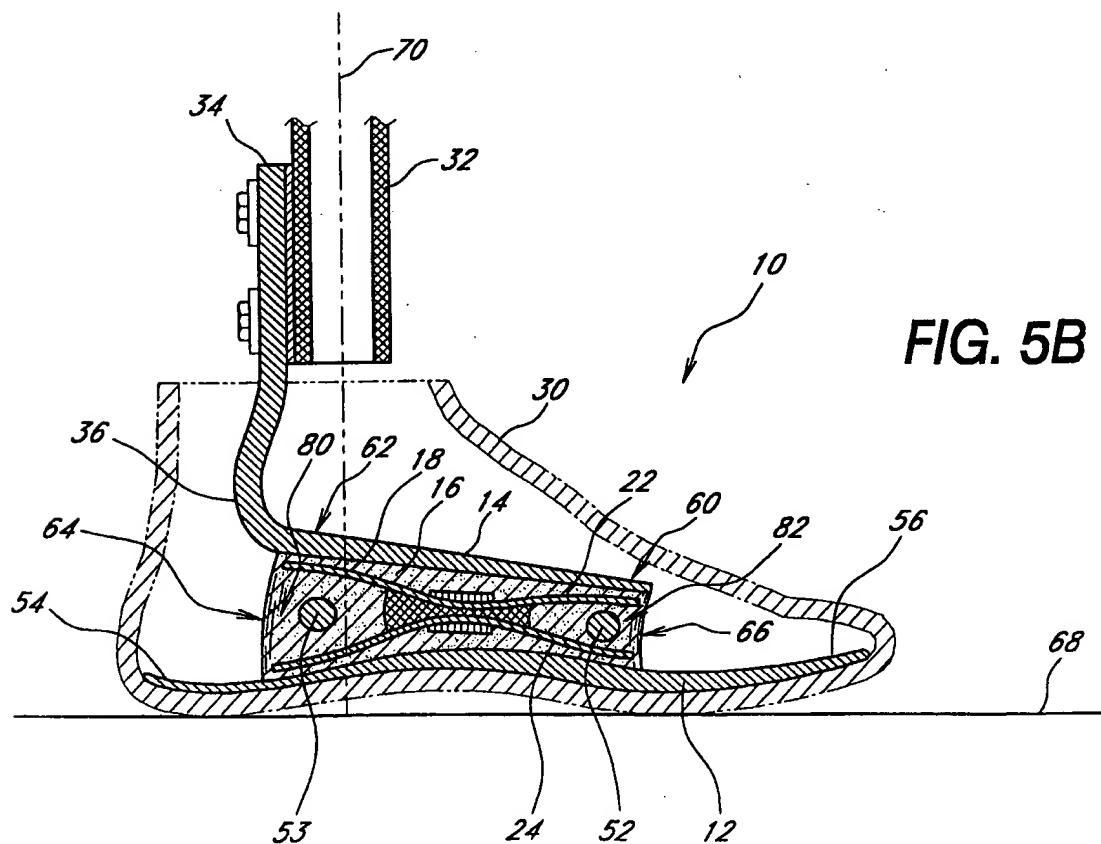


FIG. 5A**FIG. 5B**

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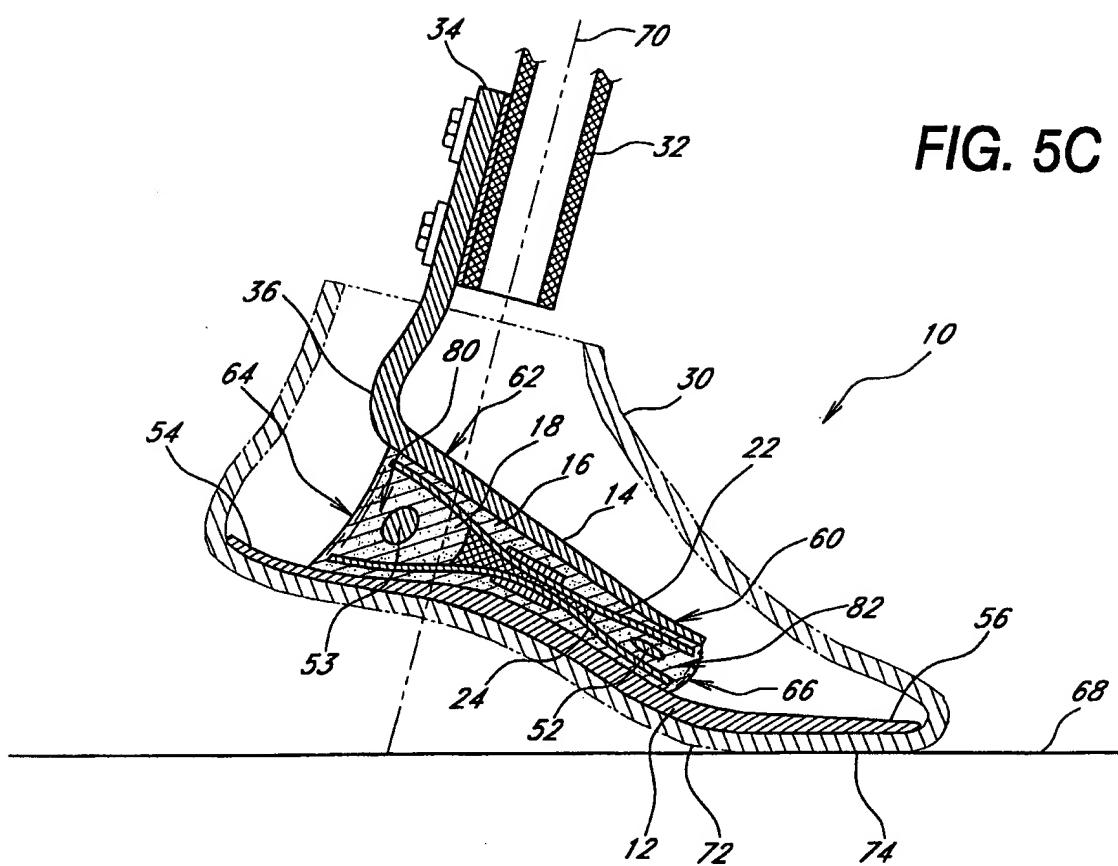


FIG. 5C

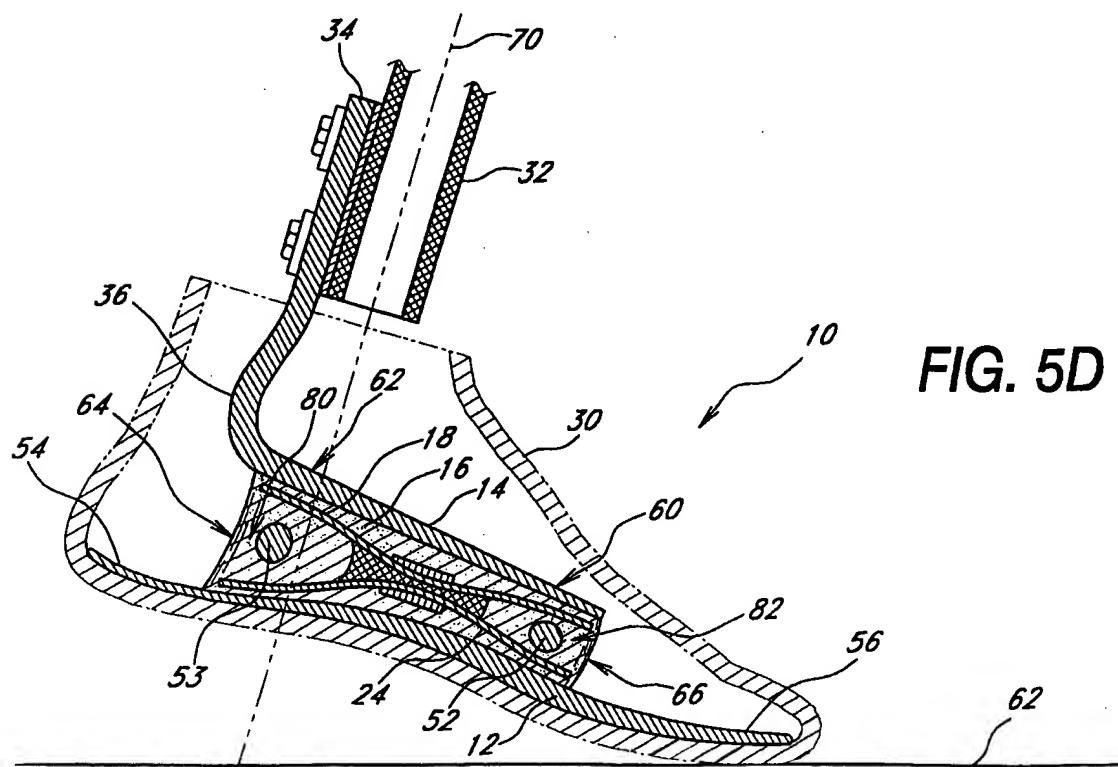


FIG. 5D

FIG. 6

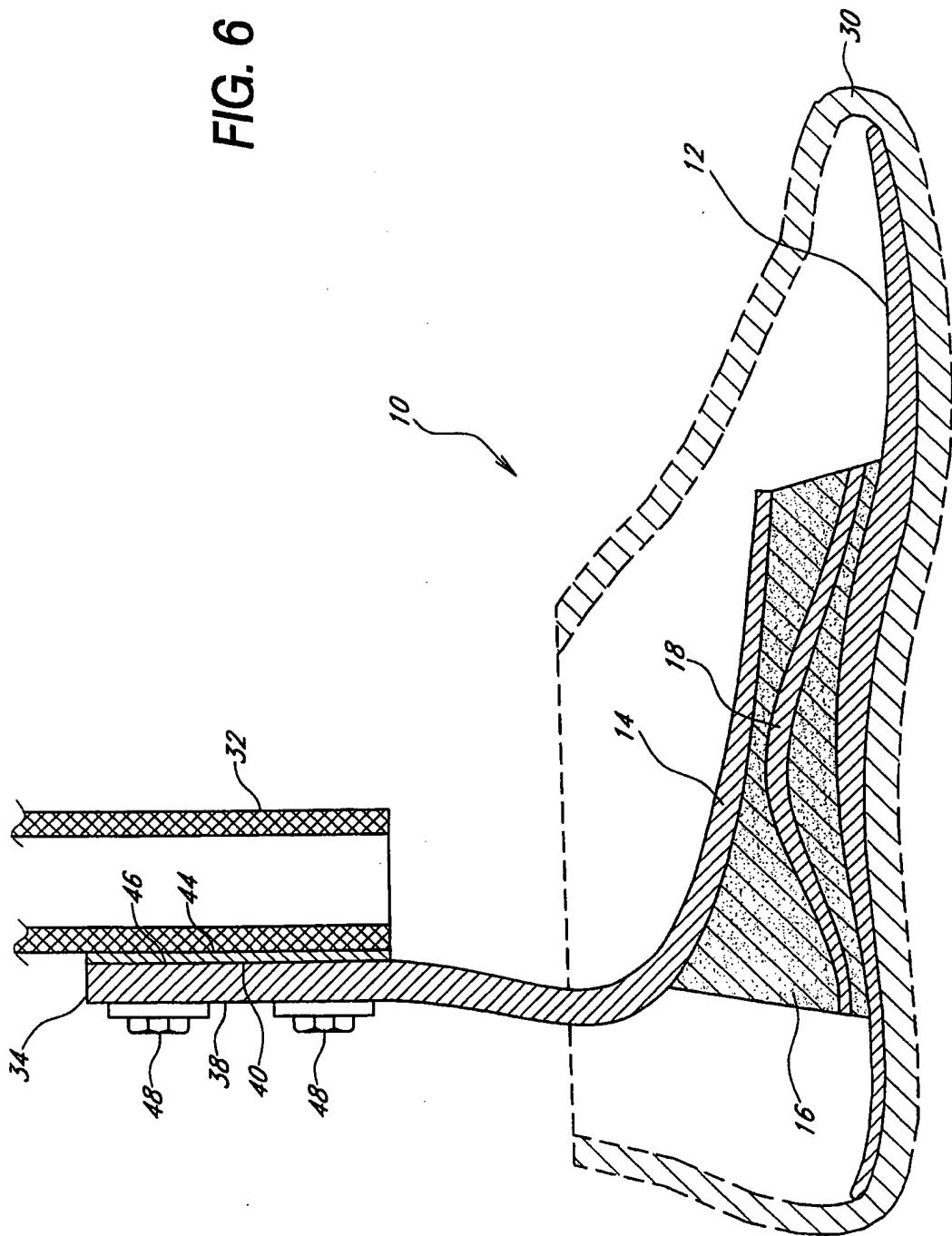


FIG. 7

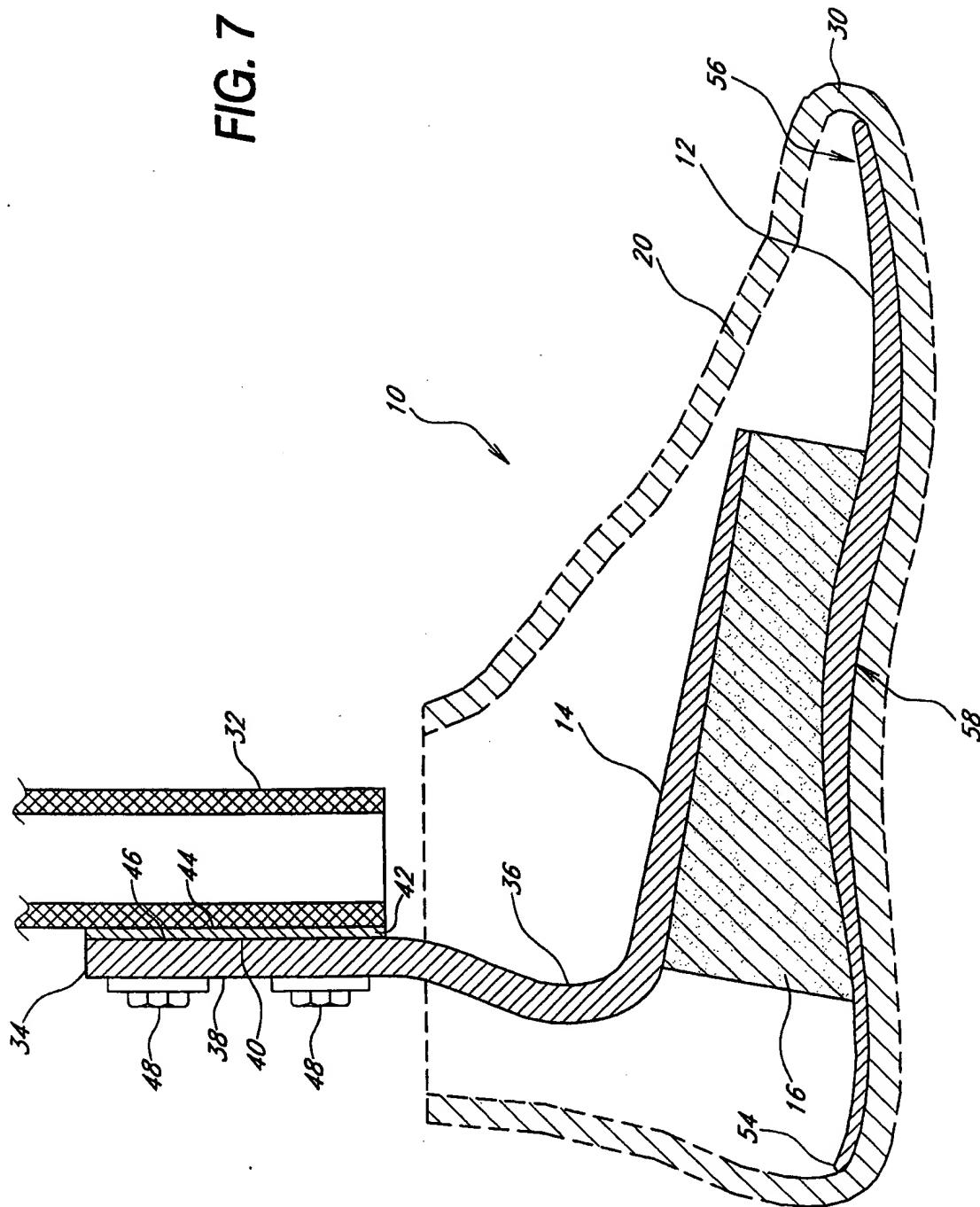


FIG. 8

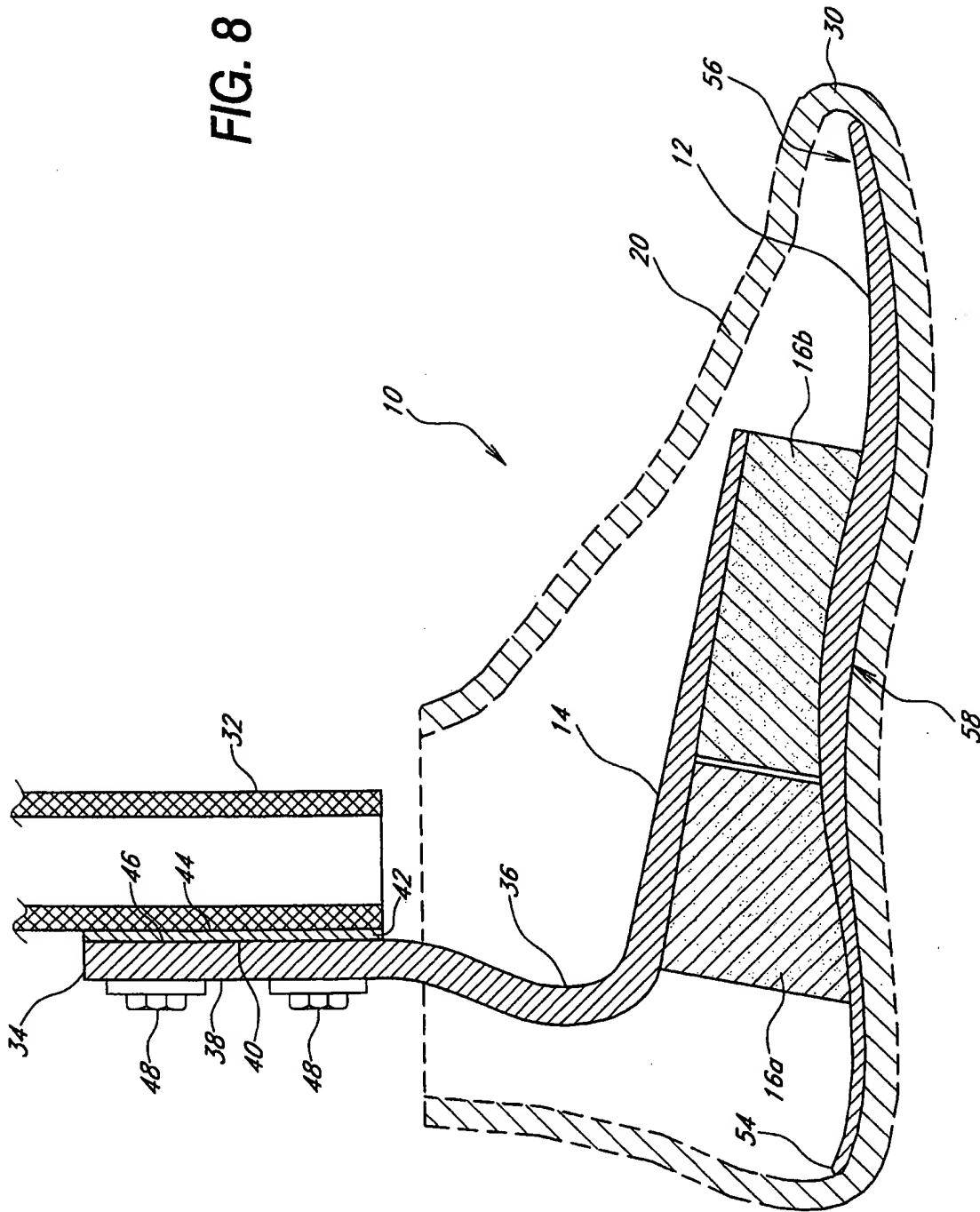
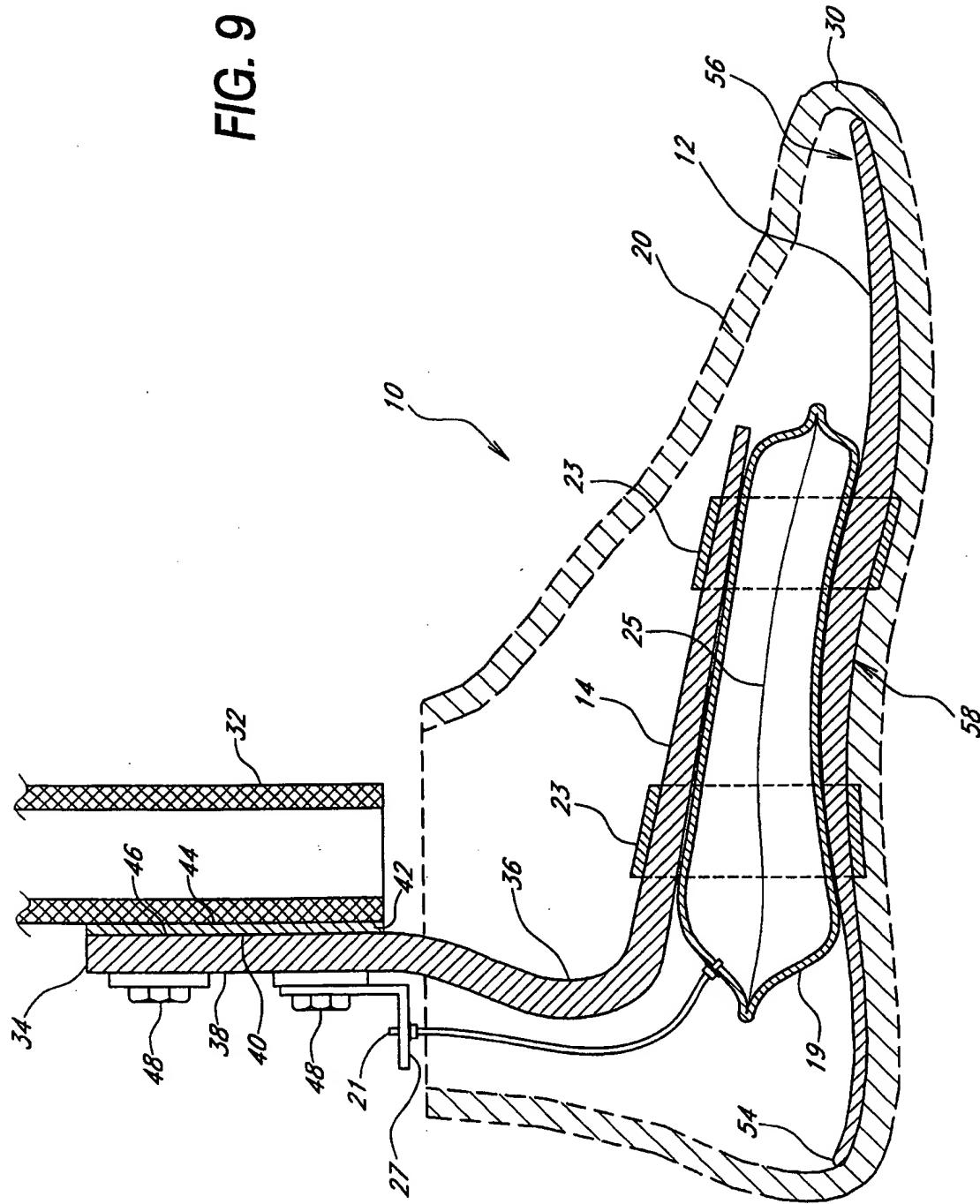
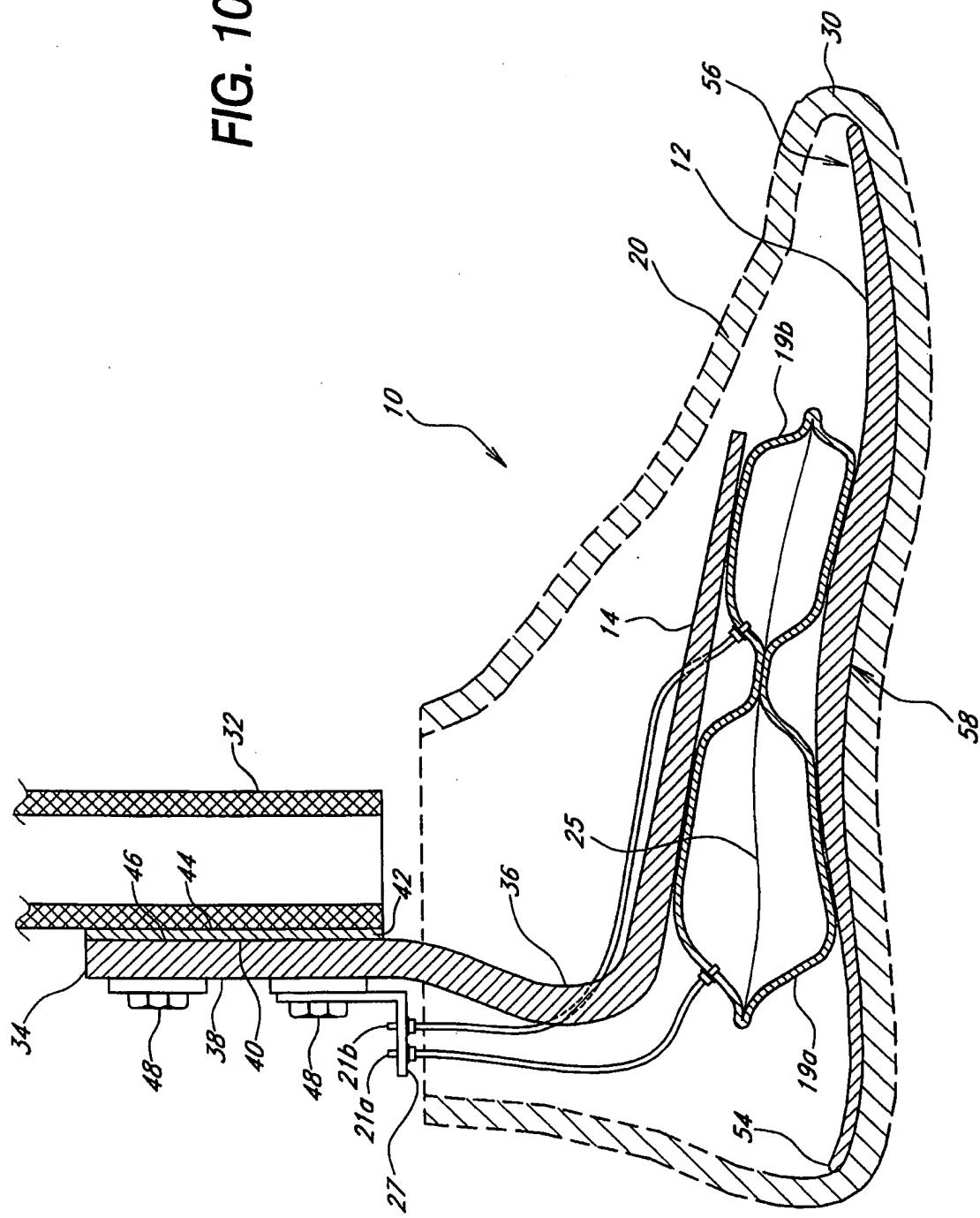


FIG. 9



11/11

FIG. 10



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/07838

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/66

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 04869 A (PHILLIPS L VAN) 22 February 1996 (1996-02-22) abstract; figures ---	1,10-14
A	EP 0 401 864 A (BOCK ORTHOPAED IND) 12 December 1990 (1990-12-12) abstract; figure 4 ---	1
A	WO 88 00815 A (OHIO WILLOW WOOD INC) 11 February 1988 (1988-02-11) abstract; figure 1 ---	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

15 July 1999

26/07/1999

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Kanal, P

INTERNATIONAL SEARCH REPORT

Int'l. Application No
PCT/US 99/07838

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SOVIET INVENTIONS ILLUSTRATED Section PQ, Week 8131, 9 September 1981 (1981-09-09) Derwent Publications Ltd., London, GB; Class P32, AN H1993D XP002109290 & SU 778 732 A (PROSTHETICS RESINS), 5 December 1980 (1980-12-05) abstract -----	1

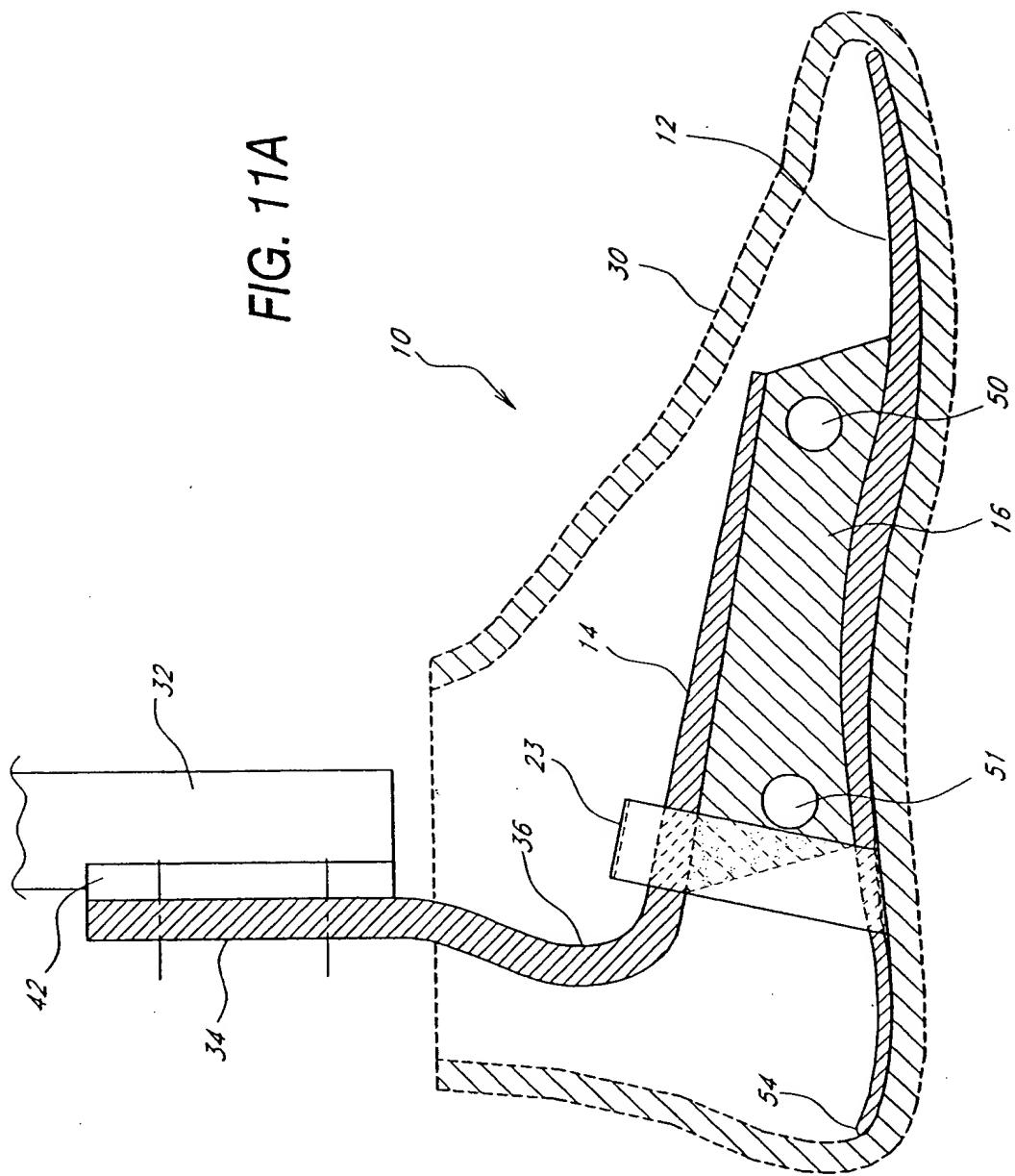
INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte:	onal Application No
PCT/US 99/07838	

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EP 0401864	A 12-12-1990	DE AT DK US	3918810 A 81961 T 401864 T 5062859 A		13-12-1990 15-11-1992 30-11-1992 05-11-1991
WO 8800815	A 11-02-1988	CA DE EP JP US	1321297 A 3784337 A 0277175 A 1500403 T 4865612 A		17-08-1993 01-04-1993 10-08-1988 16-02-1989 12-09-1989
SU 778732	A 05-12-1980		NONE		

FIG. 11A



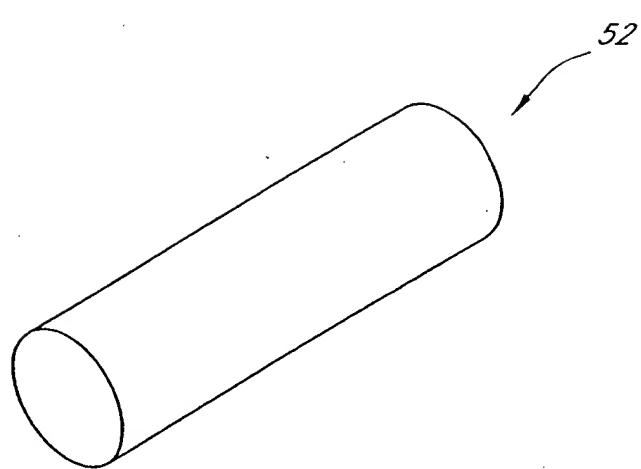


FIG. 11B

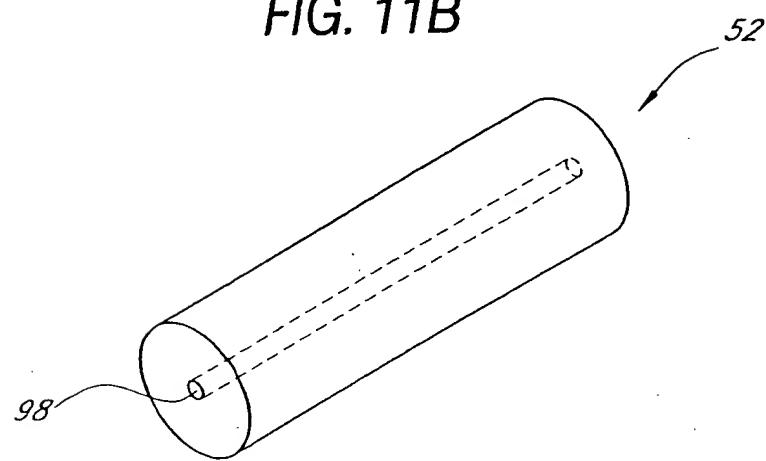


FIG. 11C

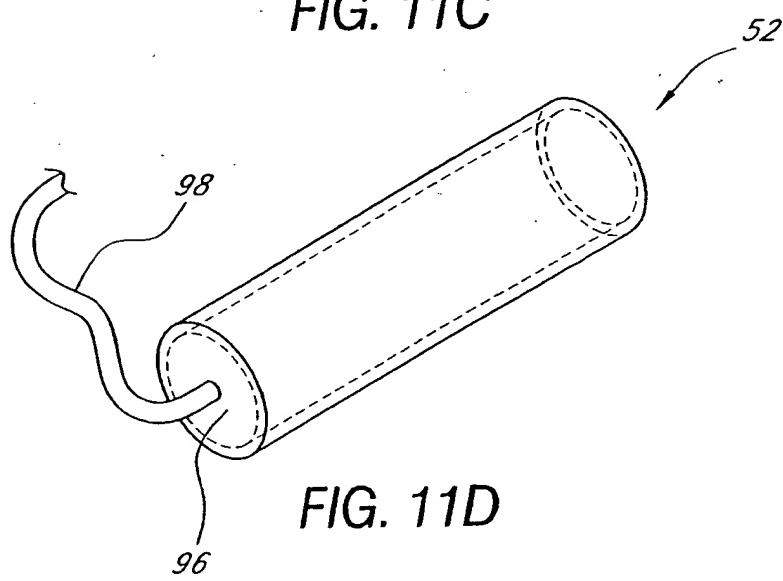


FIG. 11D

FIG. 12

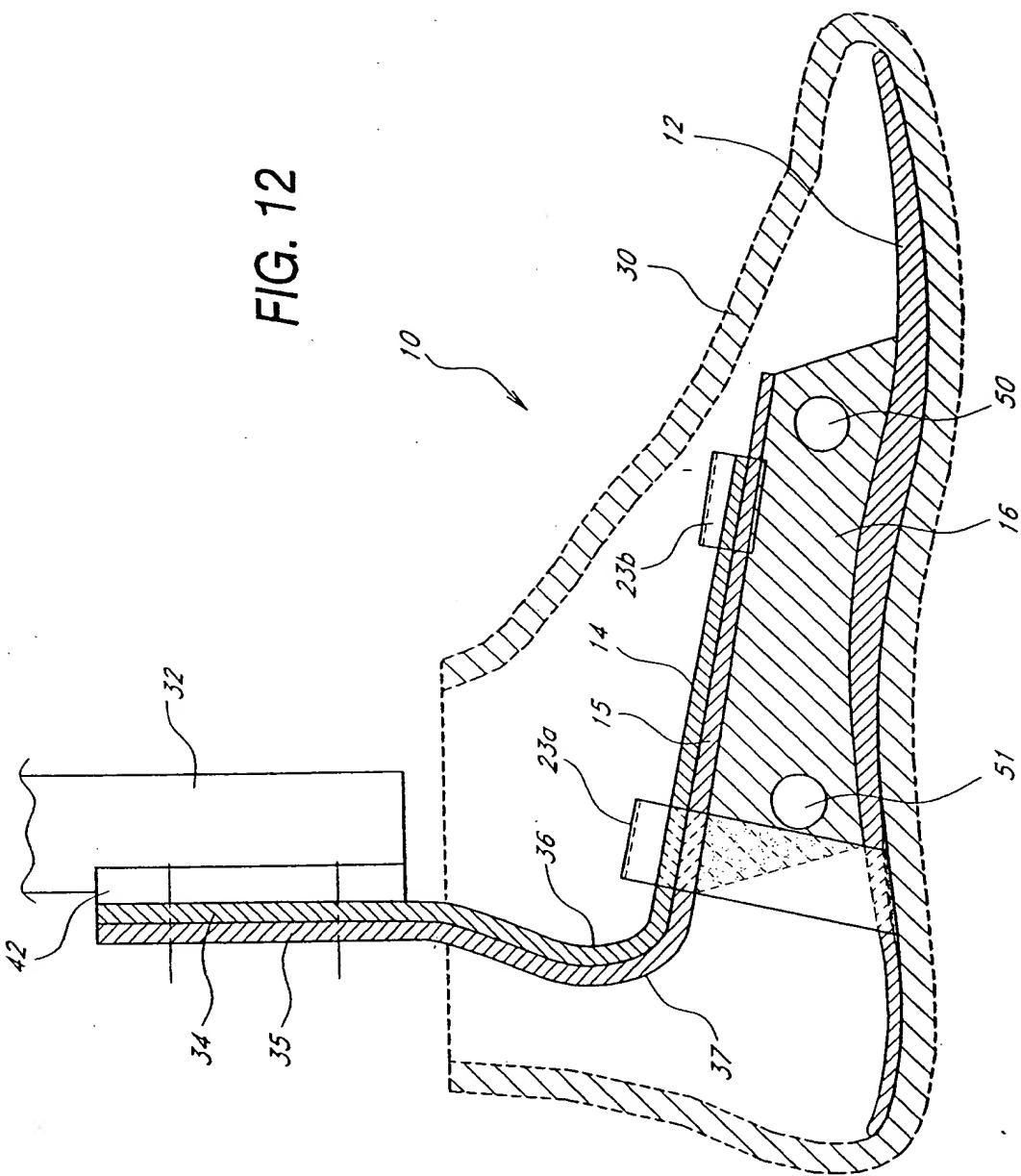


FIG. 13

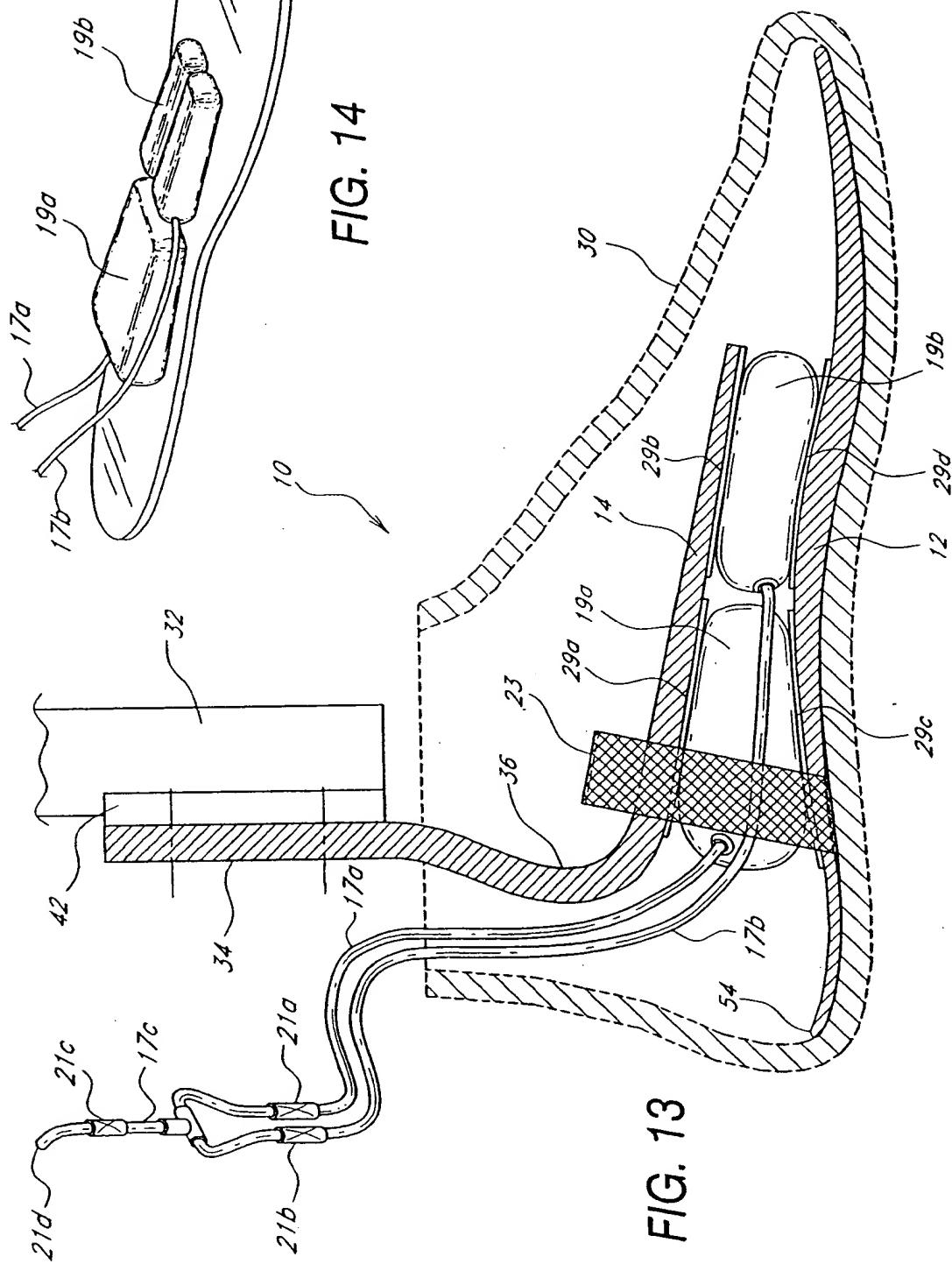
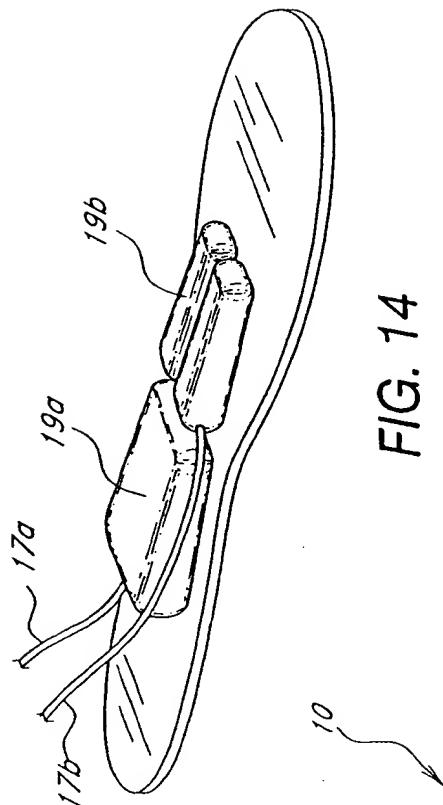
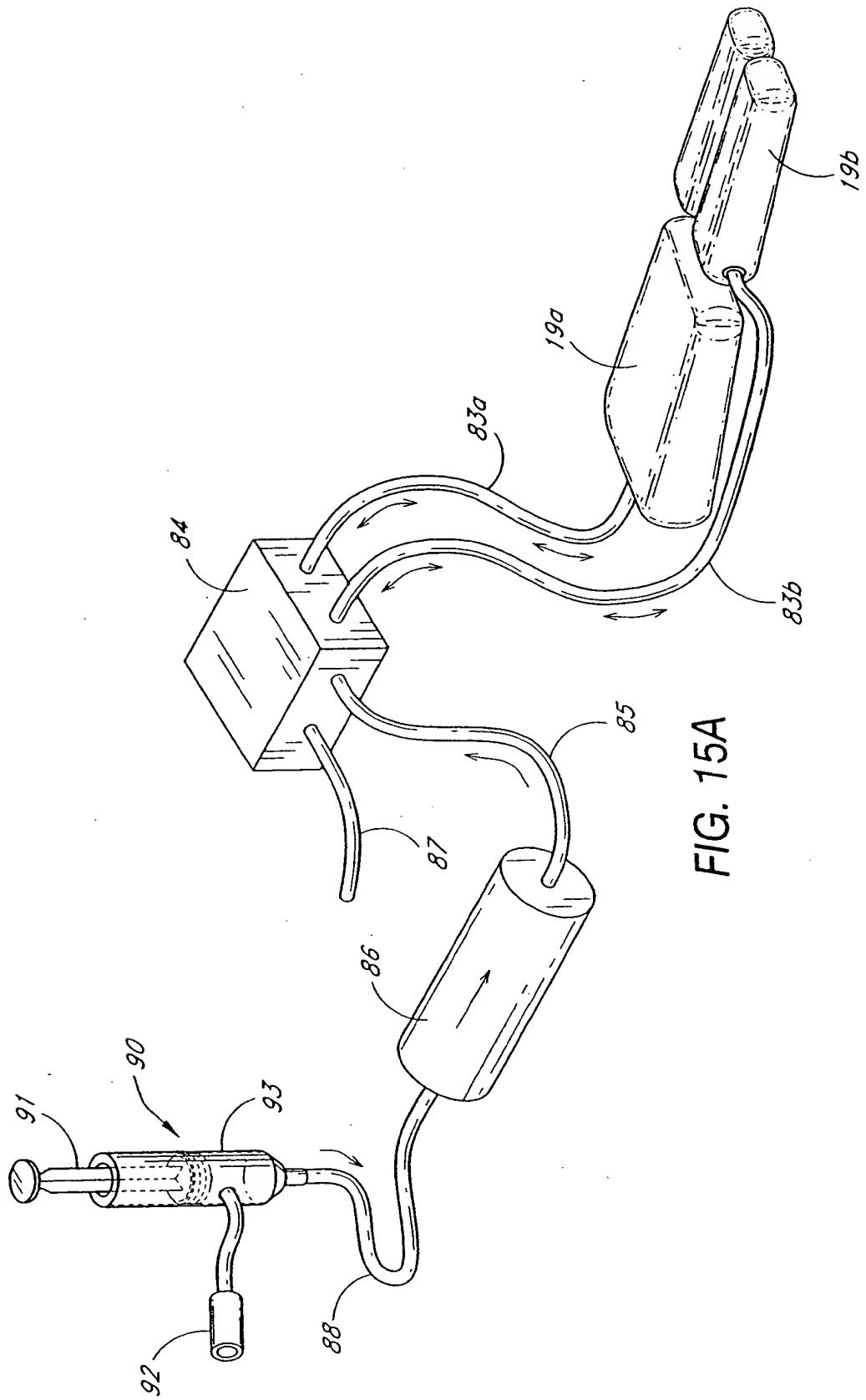


FIG. 14





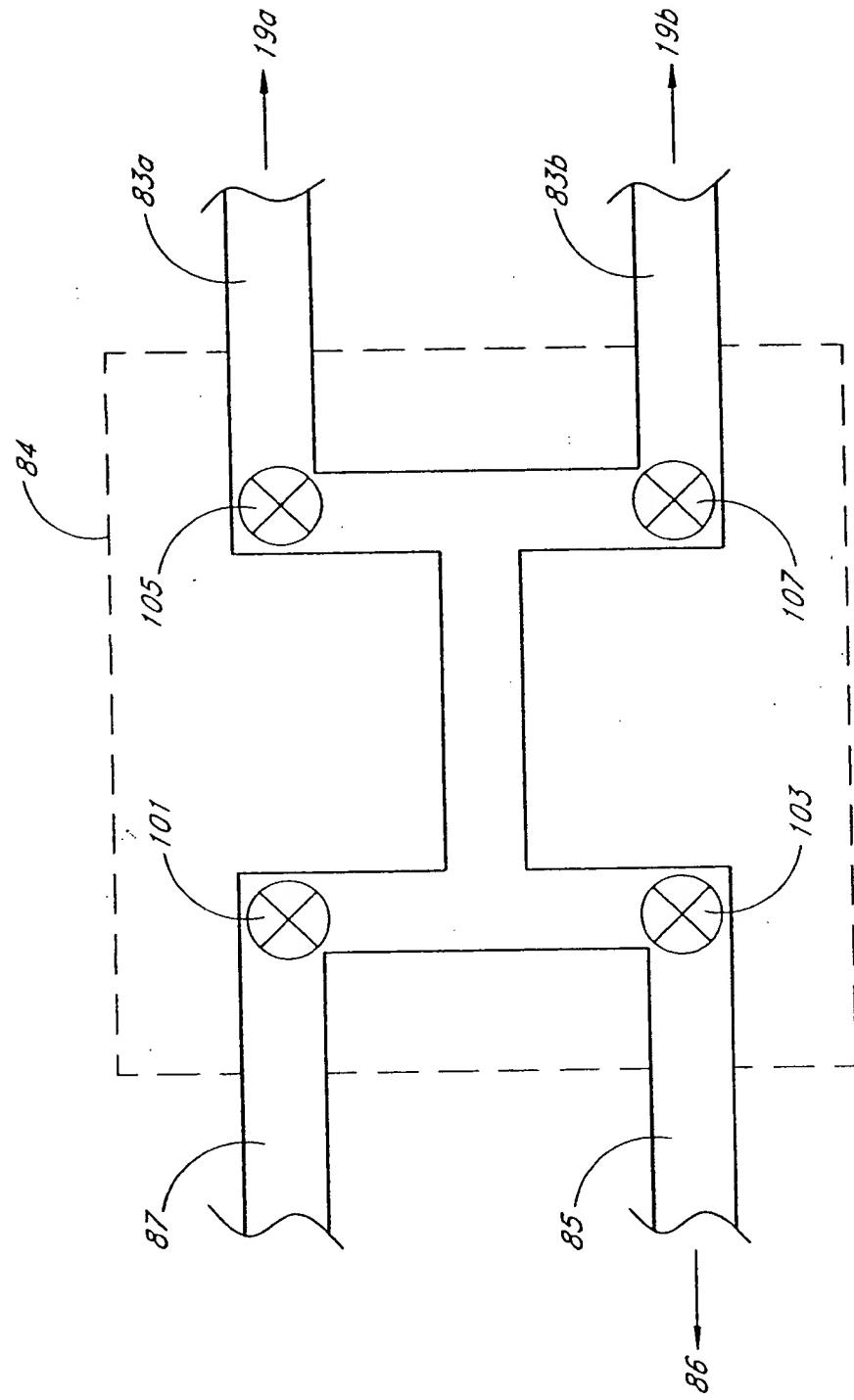


FIG. 15B

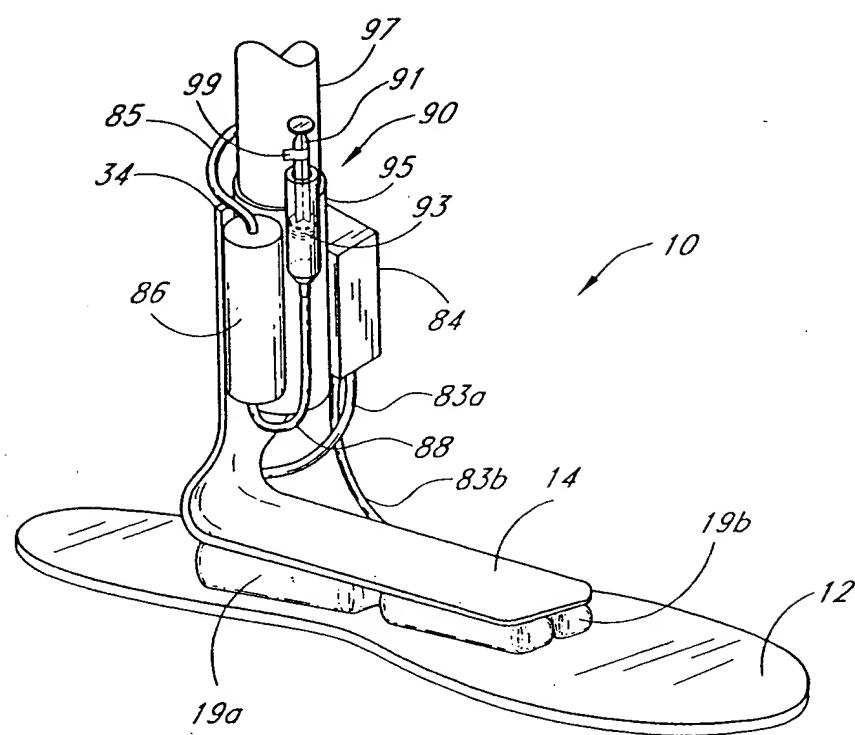


FIG. 16A

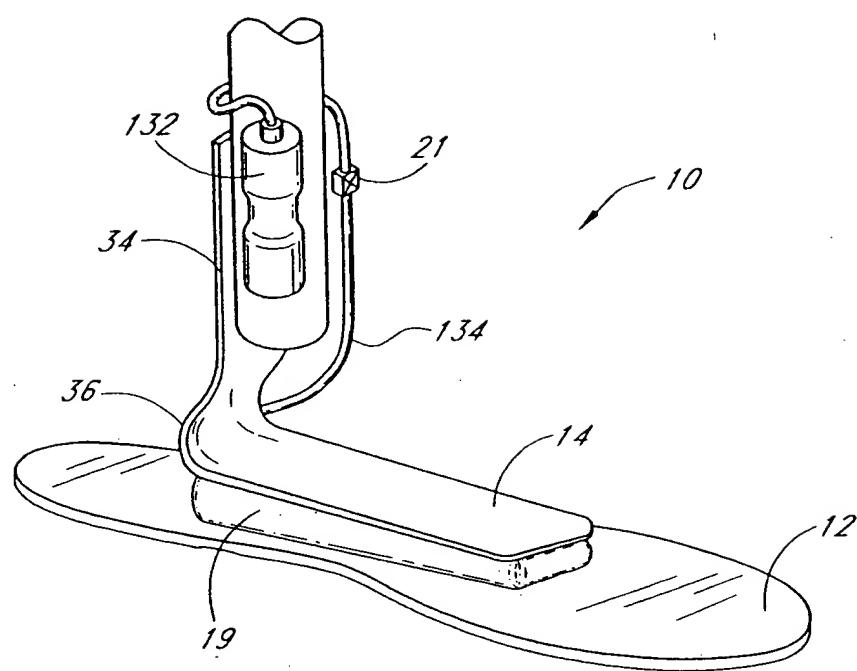


FIG. 16B

FIG. 17

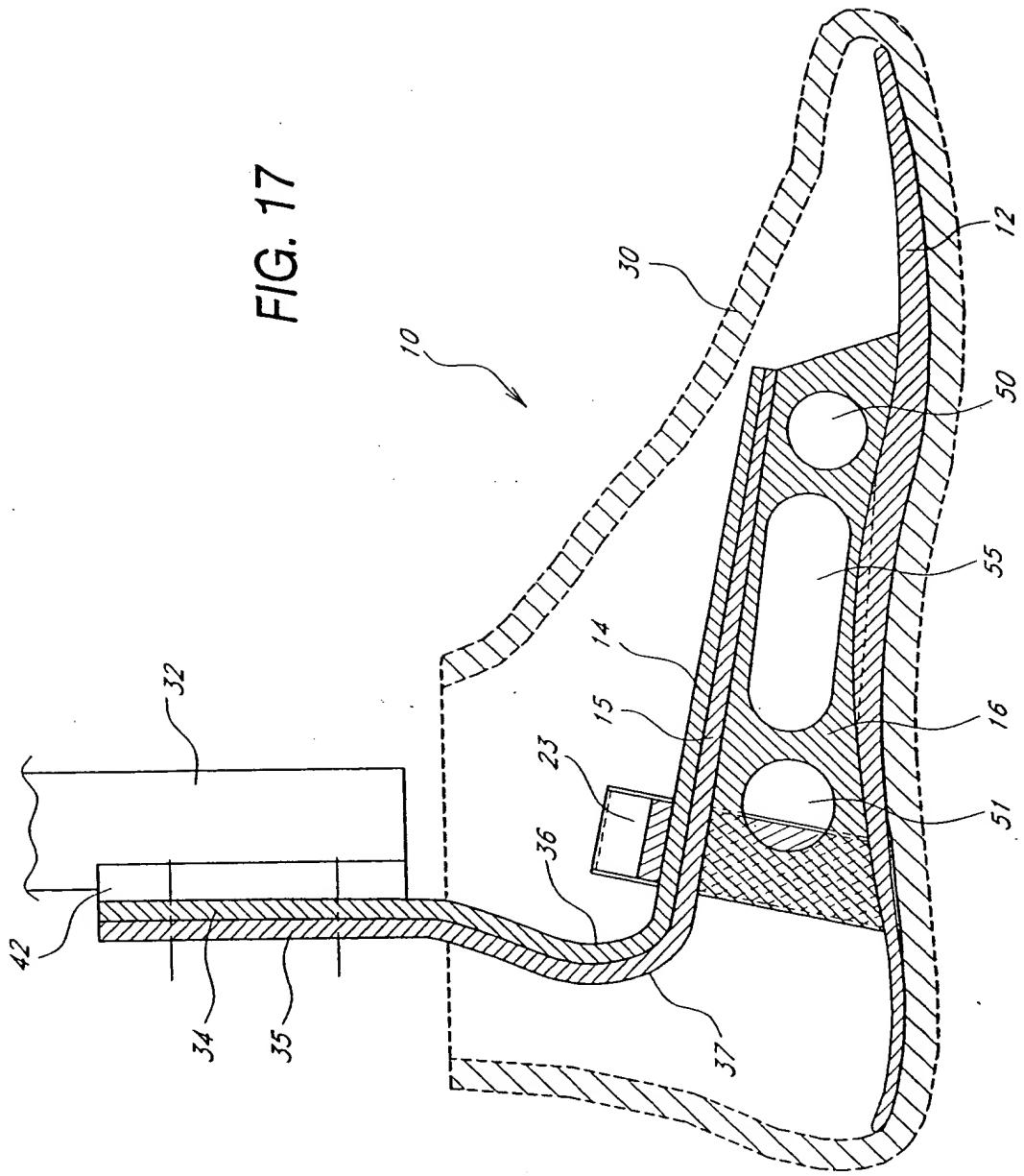


FIG. 18

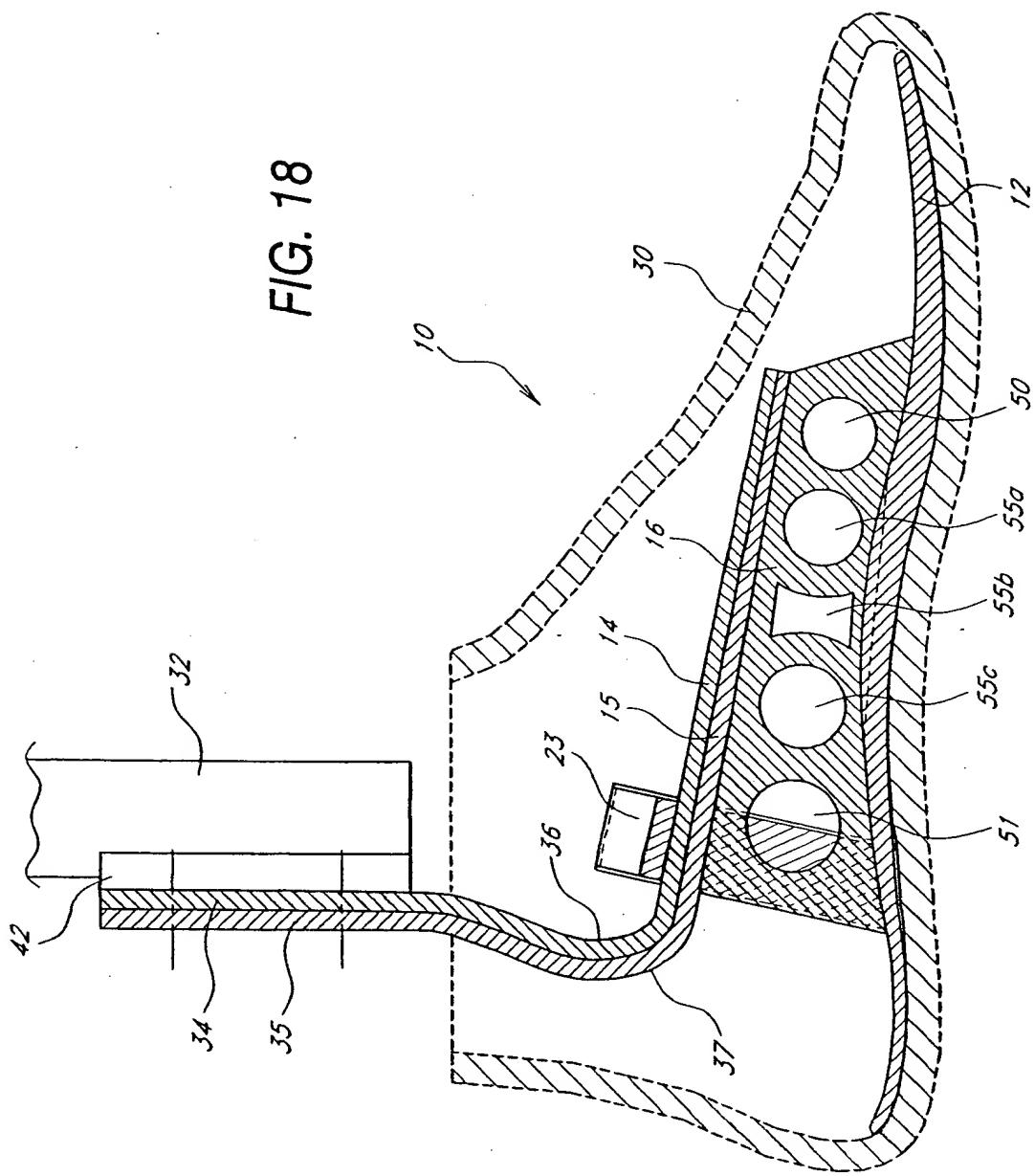


FIG. 19

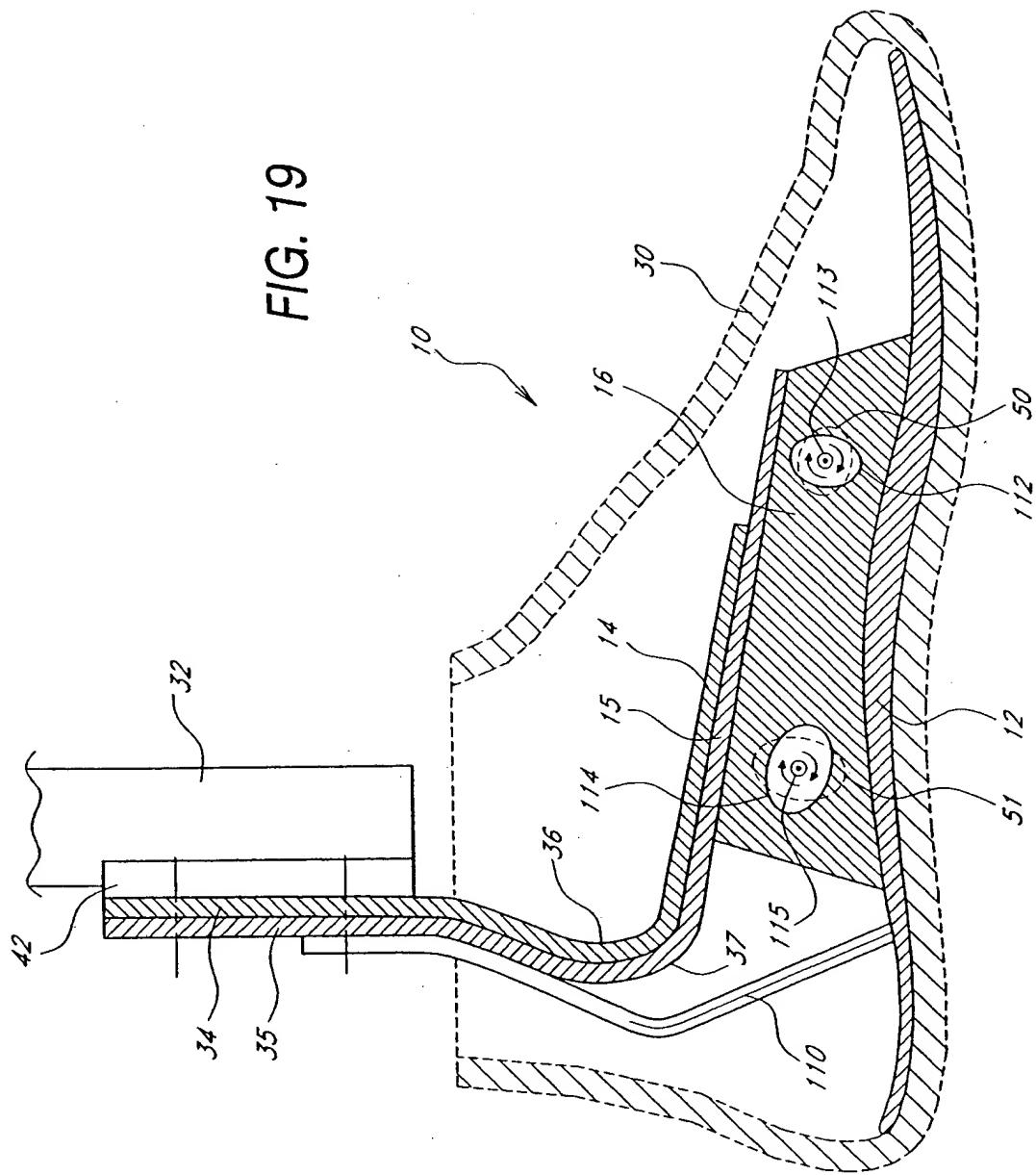


FIG. 20

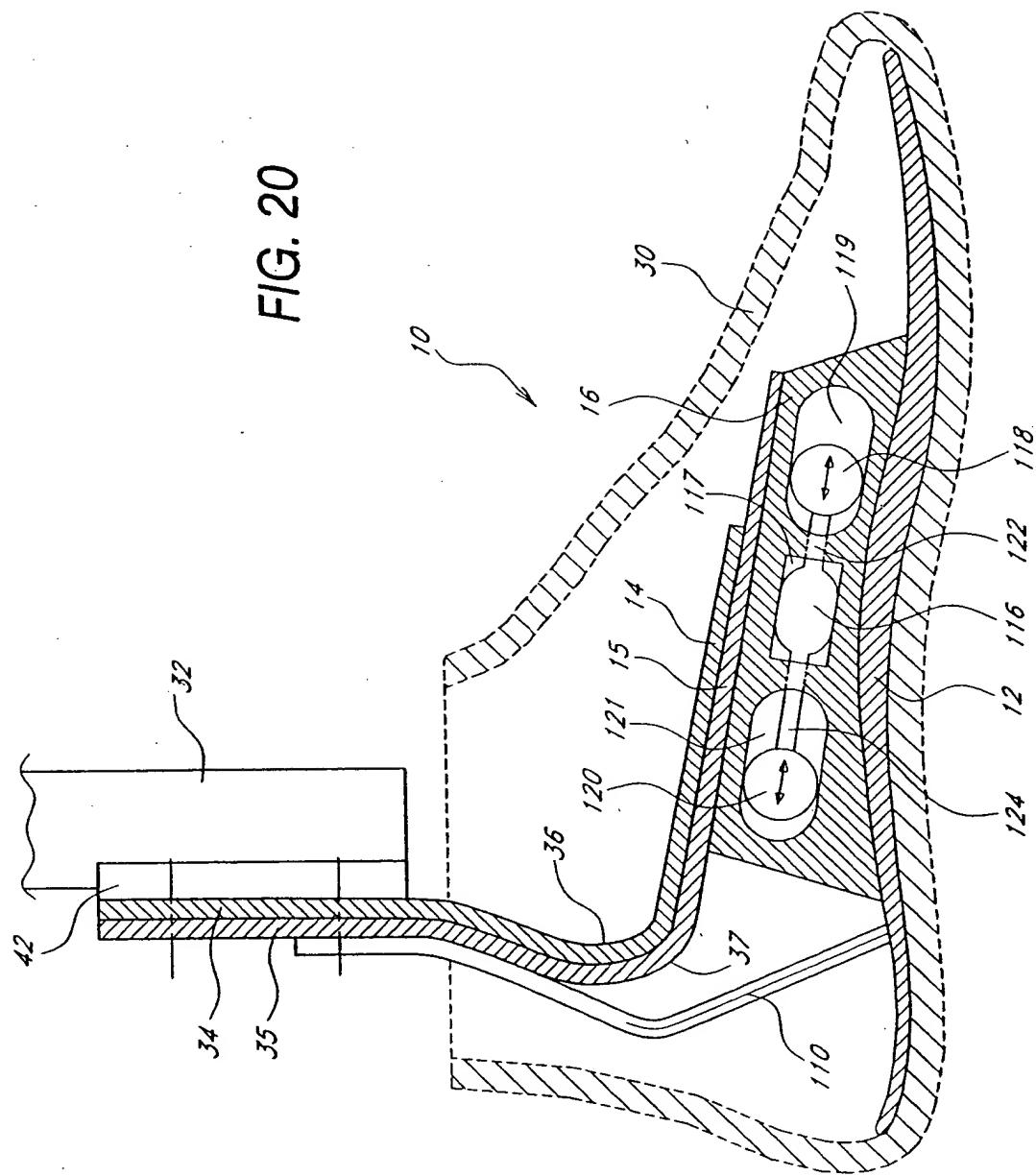


FIG. 21

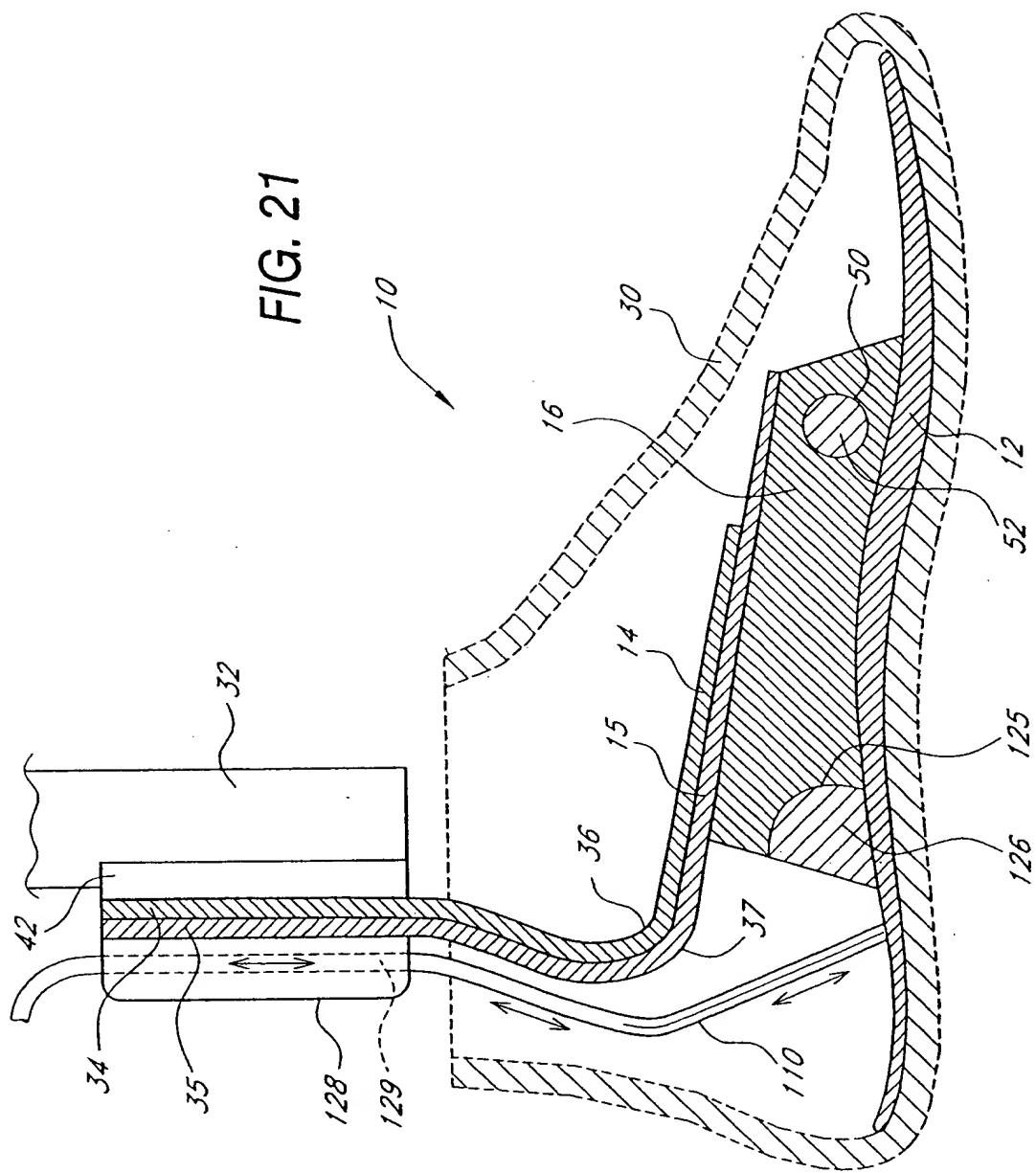
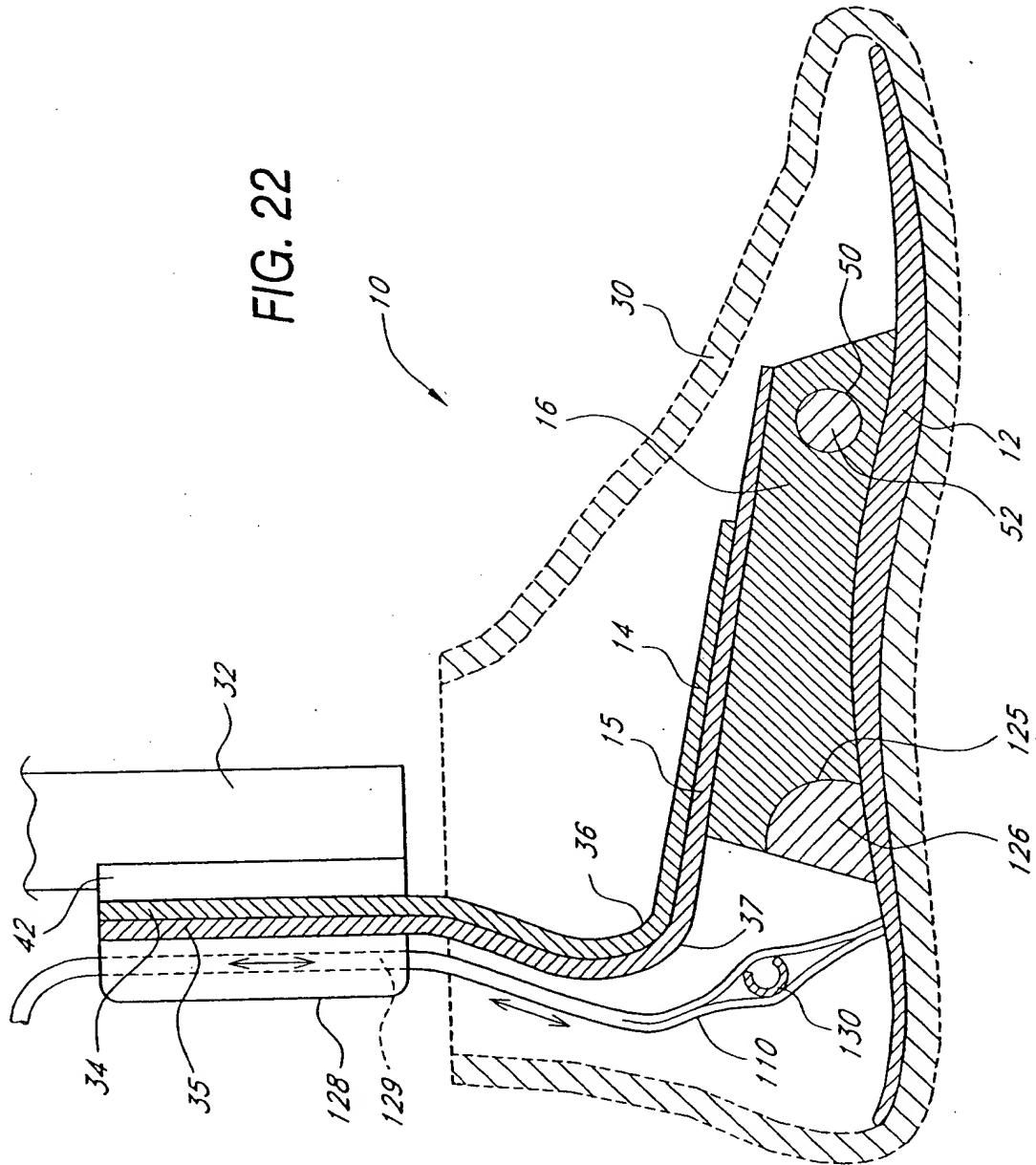
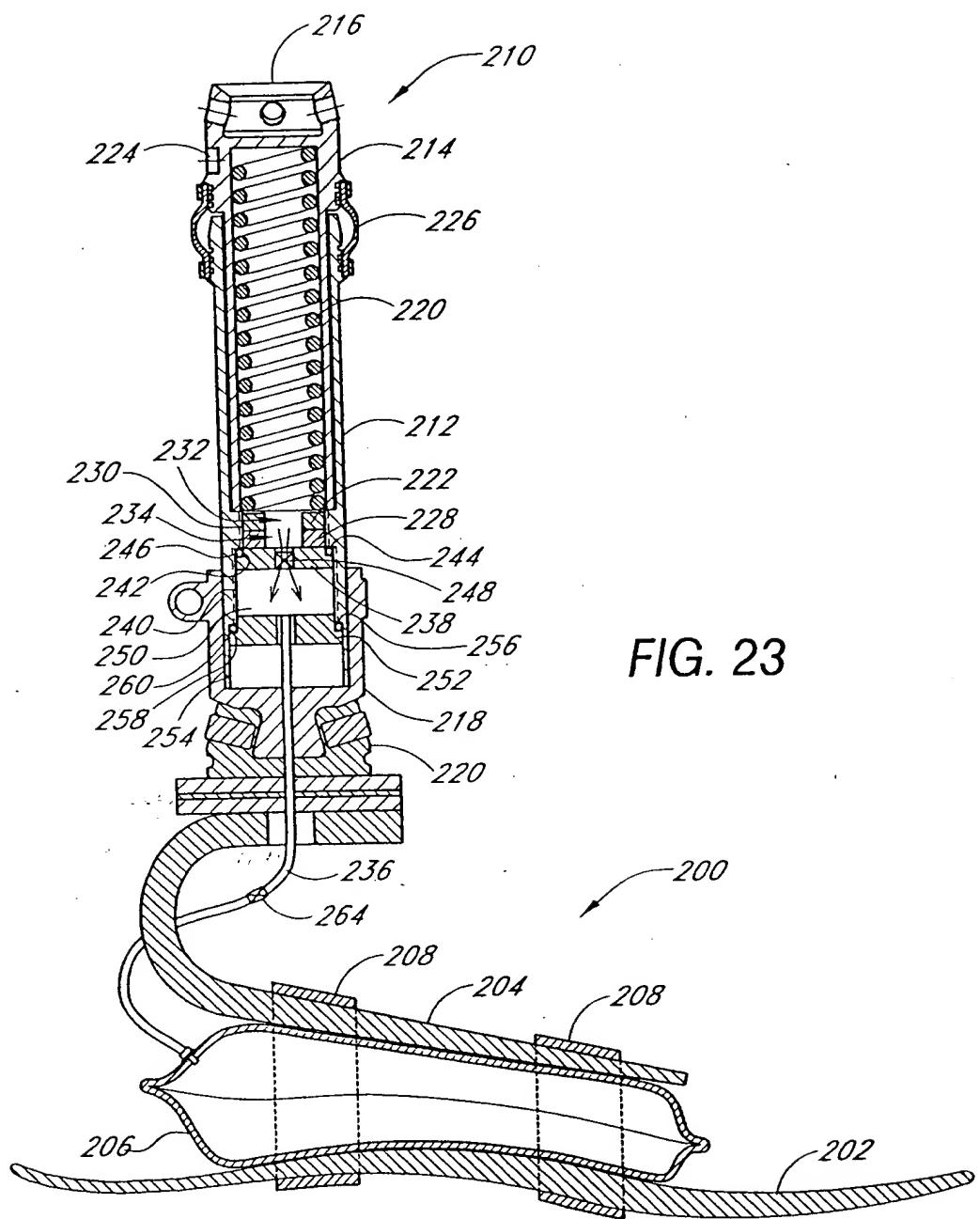


FIG. 22





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